Sunshine Act Meetings

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This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 2:00 p.m., Tuesday, June 20, 1989.
PLACE: 2033 K St., NW., Washington, DC, 8th Floor Hearing Room.
STATUS: Closed.
MATTERS TO BE CONSIDERED: Rule Enforcement Review.
CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 254–6314.

Jean A. Webb,
Secretary of the Commission.
[FR Doc. 89–13604 Filed 6–5–89; 11:22 am]
BILLING CODE 6351–01–M

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 10:00 p.m., Tuesday, June 27, 1989.
PLACE: 2033 K St., NW., Washington, DC, 5th Floor Hearing Room.
STATUS: Open.
MATTERS TO BE CONSIDERED: Regulation of Hybrid Instruments/Final Rule.
CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 254–6314.

Jean A. Webb,
Secretary of the Commission.
[FR Doc. 13605 Filed 6–5–89; 11:22 am]
BILLING CODE 6351–01–M

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 10:30 p.m., Tuesday, June 27, 1989.
PLACE: 2033 K St, NW., Washington, DC, 8th Floor Hearing Room.
STATUS: Closed.
MATTERS TO BE CONSIDERED: Enforcement Matters.
CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 254–6314.

Jean A. Webb,
Secretary of the Commission.
[FR Doc. 89–13606 Filed 6–5–89; 11:22 am]
BILLING CODE 6351–01–M

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11:00 p.m., Tuesday, June 27, 1989.
PLACE: 2033 K St., NW., Washington, DC, 8th Floor Hearing Room.
STATUS: Closed.
MATTERS TO BE CONSIDERED: Rule Enforcement Review.
CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 254–6314.

Jean A. Webb,
Secretary of the Commission.
[FR Doc. 89–13607 Filed 6–5–89; 11:22 am]
BILLING CODE 6351–01–M

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

June 2, 1989.

TIME AND DATE: 10:00 a.m., Thursday, June 8, 1989.
PLACE: Room 600, 1730 K Street, NW., Washington, DC.
STATUS: Open.
MATTERS TO BE CONSIDERED: In addition to the previously scheduled item, the Commission will consider and act upon the following:

2. *Utah Power & Light Company v. Secretary of Labor, MSHA,* Docket No. WEST 89–161–R. (Issues include consideration of Utah Power's application for temporary relief.)

It was determined by a unanimous vote of Commissioners that this item be included in the meeting and that no earlier announcement of the addition was possible.

CONTACT PERSON FOR MORE INFORMATION: Jean Ellen (202) 653–5629 / (202) 566–2673 for TDD Relay.

Jean H. Ellen,
Agenda Clerk.
[FR Doc. 89–13583 Filed 6–5–89; 8:45 am]
BILLING CODE 6735–01–M

UNITED STATES INTERNATIONAL TRADE COMMISSION

USITC SE–89–22

TIME AND DATE: Monday, June 12, 1989 at 4:00 p.m.
PLACE: Room 101, 500 E Street, SW., Washington, DC 20436.
STATUS: Open to the public.
MATTERS TO BE CONSIDERED:

1. Agenda
2. Minutes
3. Ratifications
4. Petitions and Complaints:
   Certain Doxorubicin and Doxorubicin Preparations (D/N 1508).
5. Any items left over from previous agenda.

CONTACT PERSON FOR MORE INFORMATION: Kenneth R. Mason, Secretary (202) 252–1000.

Kenneth R. Mason,
Secretary.
June 2, 1989.
[FR Doc. 89–13614 Filed 6–5–89; 12:14 pm]
BILLING CODE 7020–02–M

NATIONAL SCIENCE BOARD

TIME AND DATE:

June 15, 1989, 8:30 a.m. Open Session
June 16, 1989, 8:00 a.m. Closed Session
June 16, 1989, 8:15 a.m. Open Session

PLACE: National Science Foundation, 1800 G Street, NW., Room 540, Washington, DC 20550.

STATUS: Most of this meeting will be open to the public. Part of this meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Thursday, June 15, 1989

Open Session (8:30 a.m. to 12:30 p.m.)

1. Overview
   —NSF's Changing Role
   —Policy Environment
   —Priorities
   —Issues
2. Strategic Plan Review
   —Goals
   —Update
   —Projections
   —Agency Relationships
3. Human Resources development
   —Education
   —Minorities
   —Women
   —Undergraduate
   —Graduate Programs

Thursday, June 15, 1989

Open Session (1:30 p.m. to 5:30 p.m.)

4. Research Opportunities
   —Base Programs and Disciplinary Role
   —Centers
   —International Science Sharing
5. Roundtable: Research Frontiers
   —Global Environmental Change
   —Materials Science and Engineering
   —Math, Astronomy, Physics Programs
   —Computational Science and Engineering
   —Human Genome
6. Physical Infrastructure Requirements
   —Instrumentation
   —Capital Planning
   —Research Facilities

Friday, June 16, 1989

Closed Session (8:00–8:15 a.m.)

7. Minutes—May 1989 Meeting
8. NSB Nominees

9. Grants and Contracts

Friday, June 16, 1989

Open Session (8:15 to 12:00 noon) and 1:00 p.m. to 3:00 p.m.

10. NSB Biennial Report—Science and Engineering Indicators-1989
11. Budget Consideration
—Budget History
—Budget Outlook
—1991 Budget Assumption
12. Summary and Conclusion

Thomas Ubois,

Executive Officer.

[FR Doc. 89–13572 Filed 6–5–89; 8:45 am]

BILLING CODE 7555-01-M

federal register

Wednesday
June 7, 1989

Part II

Nuclear Regulatory Commission

10 CFR Parts 2 and 26

Fitness-For-Duty Programs; Final Rule and Statement of Policy

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 2 and 26

RIN: 3150-AC81

Fitness-for-Duty Programs

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule and statement of policy.

SUMMARY: The Nuclear Regulatory Commission (NRC) is issuing its regulations to require licensees authorized to construct or operate nuclear power reactors to implement a fitness-for-duty program. The general objective of this program is to provide reasonable assurance that nuclear power plant personnel are reliable, trustworthy, and not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties. A fitness-for-duty program developed under the requirements of this rule is intended to create an environment which is free of drugs and the effects of such substances.

The Commission is taking this action to significantly increase assurance of public health and safety. The scientific evidence is conclusive that significant decrements in cognitive and physical task performance result from intoxication due to illicit drug abuse, as well as the use and misuse of legal substances. Given the addictive and impairing nature of certain drugs, while recognizing that the presence of drug metabolites does not necessarily relate directly to a current impaired state, the presence of drugs does strongly suggest the likelihood of past, present, or future impairment affecting job activities. In addition, the NRC believes that the reliability, integrity, and trustworthiness of persons working within nuclear power plants is important to assure public health and safety. Since there is an underlying assumption that workers will abide by the licensee's policies and procedures, any involvement with illegal drugs shows that the worker cannot be relied upon to obey laws of a health and safety nature, indicating that the individual may not scrupulously follow rigorous procedural requirements with the integrity required in the nuclear power industry to assure public health and safety. In addition, the Commission is revising its enforcement policy to reflect this fitness-for-duty rule.

EFFECTIVE DATE: July 7, 1989. The information collection requirements in this final rule do not become effective until they are approved by the Office of Management and Budget (OMB). The NRC will announce the date that the information collection requirements are approved in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Loren Bush, Reactor Safeguards Branch, Division of Reactor Inspection and Safeguards, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 492-0944.

SUPPLEMENTARY INFORMATION:

Background

On September 22, 1988, the Nuclear Regulatory Commission published in the Federal Register (53 FR 36795) proposed amendments that would issue a new regulation 10 CFR Part 26, "Fitness-for-Duty Program," which would require licensees who are authorized to operate nuclear power reactors to implement a fitness-for-duty program that met uniform standards established by the rule to promote the public health and safety.

Interested parties were invited to submit comments in connection with the proposed amendments within 60 days after publication in the Federal Register. There were a total of 3,079 comments made by 378 responders and attendees during a public meeting held on October 17, 1988. A detailed summary and analysis of the comments are contained in NUREG-1354, "Fitness-for-Duty in the Nuclear Power Industry: Responses to Public Comments." Upon consideration of the comments received both in writing and during the public meeting and other factors involved, the Nuclear Regulatory Commission has adopted the proposed regulations, with certain modifications generally set forth below.

Copies of NUREG-1354 may be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-7082. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161. A copy is also available for public inspection and/or copying at the NRC Public Document Room, 2120 L Street NW., lower level of the Gelman Building, Washington, DC.

Comments and Responses to the Proposed Rule

1.0 General Overview

Summary of Comments

The NRC received 378 comment letters in response to the Notice of Proposed Rulemaking (NPRM). The NRC considered all comments submitted in a timely manner in response to the NPRM and comments and questions received during a public meeting on the draft rule held by the NRC. The comment period for the NPRM closed on November 21, 1988.

Comments were received from the general public; from workers in nuclear power plants; from union locals, national and international headquarters of unions; from the Nuclear Management and Resources Council (NUMARC), 55 power reactor licensees, several non-power reactor licensees; from several vendor and contractor organizations; and from other interested parties.

There were several major issues presented by the commenters. These are summarized along with the NRC responses in the sections that follow. An overview of these comments is provided in this section.

Of primary concern to roughly half of all commenters was the requirement for random drug testing. Although these commenters clearly objected to the use of illegal drugs within the nuclear power industry, this provision of the proposed rule drew a strong negative reaction from private citizens, labor unions, and workers covered by the proposed rule. Vigorous objections were stated based on the perceptions of invasion of privacy and conflict with Constitutional rights resulting from the drug testing provision. Many of these commenters stressed that the level of substance abuse in the nuclear power industry is insufficient to justify such strong action, that nuclear power plant workers have demonstrated their reliability over the years, and that it is both demoralizing and insulting to require proof of their reliability through random drug tests. Other issues were raised concerning the legality of the proposed rule, including its relationship to labor laws and state and local statutes. These objections are summarized more fully in the following sections.

Those commenters opposing random testing were usually supportive of one or more alternatives. Foremost among these was a combination of supervisor behavioral observation and for-cause testing. While a few commenters opposed chemical testing of any type, most of the commenters, including union organizations and members, expressed support for for-cause testing. Preaccess authorization testing also received some support and very little opposition.

A major criticism of the proposed rule was raised concerning whether the NRC was basing the rule on concerns about on-the-job impairment or on concerns

about basic employee reliability, or even upon more general concerns with public morality. Some commenters expressed the opinion that off-site drug use should not be a concern of the NRC, and that the NRC should not require a testing program that is not directly oriented to detecting current impairment.

In contrast, most licensees and NUMARC provided general support for the provision for random testing, viewing it as an effective deterrent to the use of illegal drugs. However, they did object to the possibility that they would be too severely limited by the provision that licensee testing programs must follow the HHS Guidelines. They wanted greater flexibility in the establishment of cut-off levels and the panel of drugs to be covered. Most of the licensees expressed concern over the testing rate to be required by the rule, indicating that it should be at an annual rate equivalent to or less than 100 percent of the workforce subject to testing. They further objected to any provisions that would make the licensee responsible for providing employee assistance program services to contractor personnel and objected to the extent and type of training required by the proposed rule. Other issues raised and more detail on these issues are provided in the sections that follow.

2.0 Need for Rule

2.1 Summary of Comments

A number of commenters raised the issue that there was insufficient evidence of a drug abuse problem in the nuclear power industry to justify the need for the rule. Several commenters indicated that the NRC has failed to establish a factual record regarding the nature and extent of the drug abuse problem. Also mentioned was the opinion that the apparent lack of uniformily among nuclear utility programs is not sufficient justification by the NRC for the rule.

2.2 Summary of Responses

Although drug use among nuclear power plant workers may not be as widespread as in other segments of the population, the NRC does have information to indicate that there is a sufficient problem in the nuclear power industry to warrant the fitness-for-duty rule. For example, data provided by one licensee indicates that 47 of approximately 4,000 random tests of employees were positive, 4 percent of the applicants for employment have tested positive for drug use, and 30 employees and 60 contractors tested positive for cause. Pre-access testing of nearly 12,000 contractor personnel resulted in a 5 percent positive rate. Another licensee reported that approximately 2 percent of approximately 5,000 tests of employees and contractors were positive, 179 persons tested positive for cause, and that the drugs involved included PCP, marijuana, cocaine, amphetamines, barbiturates, alcohol and other drugs. Nationally, among licensees implementing random drug testing programs, an average of around 1 percent of the random tests are positive.

In the first nine months of 1988 there were 387 events involving drugs and alcohol reported to the NRC. These events included licensee and contractor employees in all organizational levels and disciplines. Of particular concern to the NRC is that during the last year (1988), 11 licensed reactor operators were reported as being involved with drugs and two were reported as abusing alcohol; none were using these substances while on duty.

The number of significant events reported to the NRC that involve drug use or abuse has been increasing dramatically since 1985. There was a 44 percent increase in reported events between 1985 and 1986. A 73 percent increase was experienced in 1987. This increase appears to be related to the emphasis on fitness for duty by nuclear power licensees and the recently revised safeguard reporting requirements that contained explicit guidance for reporting of drug-related events. However, the increase may also be an indication of an increase in the incidence of drug problems at nuclear power plants.

These data provide sufficient evidence of a significant level of drug use by those employed in the nuclear power industry to support the need for a fitness-for-duty rule. Pursuant to the NRC's statutory authority to protect the public health and safety, the NRC must acknowledge that nuclear power plant workers are not immune to, nor insulated from, drug use or abuse of substances that may affect safety-critical job performance. The NRC believes that any drug use in the nuclear power industry warrants prevention and proactive intervention by the NRC to ensure public safety. The NRC believes that this view is consistent with the increasing awareness of nuclear power licensees that have, as addressed in their comments, drug testing and rehabilitation programs for their workers.

3.0 Impairment vs. Reliability

3.1 Summary of Comments

A number of commenters questioned whether certain provisions of the rule, such as random drug testing, were based on concern over on-the-job impairment or were based on concern over the reliability and trustworthiness of the worker. One set of commenters expressed the strongly held belief that mandatory chemical testing is only appropriate if there is evidence to suggest that workers are impaired on the job. Commenters also stated that, because urinalysis does not measure impairment, the detection of illicit drug use through urinalysis is irrelevant to the safe operation of nuclear power plants, and thus should not be an element of the rule. Two commenters requested further evidence regarding the impact of off-the-job drug use on job performance. One commenter stated that, although a positive urinalysis test result does not establish whether an individual was impaired at the time that the sample was given, it allows the employer to determine drug use and conclude reasonably that the possibility exists for future impairment which can impact workplace safety.

Other commenters noted that impairment is not the sole issue. A fundamental concern of drug abuse predominantly relates to the reliability and trustworthiness of the worker who knowingly uses drugs which are illegal. Several commenters, including NUMARC, noted the importance of worker reliability and trustworthiness in an access authorization program, and stated that the use of illegal drugs on or off the job could adversely affect the safety of nuclear power plant operations, or adversely reflect on the integrity, reliability and trustworthiness of workers with unescorted access who are responsible for nuclear power plant safety.

A number of commenters objected to specific wording in the proposed rule related to impairment. These commenters stated that the term "impairment" is imprecise and subject to various interpretations. Another commenter stated that few nuclear power plant workers are qualified to make a judgment of worker impairment, and that the term presumes an initial standard by which the worker's job performance can be measured.

3.2 Summary of Responses

The NRC recognizes that illicit drug abuse and the misuse of legal substances such as alcohol, prescription drugs, and over-the-counter medications can impair workers in the performance of their safety-related duties and result in significantly reduced workforce reliability. The scientific evidence is conclusive that significant decrements

in cognitive and physical task performance result from intoxication due to illicit drug abuse, as well as the use and misuse of legal substances. The NRC understands that, except in the case of alcohol, chemical test results do not reveal any direct information regarding drug impairment per se. However, the NRC disagrees with the argument made by commenters that, as a result, chemical tests do not provide information that is relevant to a fitness-for-duty program. The NRC believes that the reliability, integrity, and trustworthiness of workers within nuclear power plants are important to public health and safety. The granting of a license is based on the assumption that workers will abide by the licensees' policies and procedures in all areas. Indications of lack of reliability, integrity or trustworthiness, therefore, even so far as they pertain to off-site behaviors, are relevant to the NRC's need to assure that nuclear power plants are operated safely. The relationship between reliability, integrity and impairment is by no means indirect in the case of drug abuse. Most of the substances under consideration are either physically or psychologically addictive to many individuals. The NRC cannot be confident of the individual's ability to limit the use of addictive substances to situations that do not adversely affect plant safety.

Illegal drug use can result in on-duty impairment. There is a possibility that a worker who uses illegal drugs off-duty may be impaired from those drugs while on-duty, and, even if the worker does not use drugs while on duty he or she may be impaired from either hangover or withdrawal effects associated with drug use. In addition to impairment, any illegal drug use establishes that the worker cannot be relied upon to obey laws of a health and safety nature, indicating that the worker also may not be reliable in terms of scrupulously following the rules and regulations that have been established in the nuclear workplace to ensure the protection of public health and safety. For these reasons, a worker who uses illegal drugs may not be sufficiently trustworthy or reliable to perform his or her duties on the job in a manner that assures public health and safety. In contrast, the legitimate use of legal drugs does not automatically demonstrate this lack of reliability. However, workers who do use alcohol or legal drugs are expected to use those substances responsibly. Irresponsible use of these substances in a manner that results or is likely to result in on-duty impairment, or otherwise demonstrates a disregard for public health and safety, is considered substance misuse within the scope of this rule.

The debilitating effects of long-term drug abuse are also well documented in the scientific literature, and have the potential for affecting complex physical and cognitive functions long after the effects of acute intoxication have dissipated. For example, residual effects of intoxication may persist when the worker returns to work the following day. Hangover effects, withdrawal symptoms, and cycles of drug abuse and abstinence can also result in decreased reliability and diligence. Off-site drug use may also result in increased absenteeism, medical costs, and staffing requirements, thus having adverse effects on overall workforce reliability. Ultimately, drug abuse directly and indirectly affects activities which bear on safety. It is therefore a reasonable conclusion that the abuse of illicit drugs and the misuse of licit drugs pose safety concerns in the nuclear power industry and is predictive of a lack of reliability, integrity, and trustworthiness.

The wide range of potential on-the-job impairment is complex in nature and difficult to observe, and therefore requires a broad approach to assure nuclear power plant safety. In addition to supervisory observation, other means are required to detect drug abuse, psychological stress, and physical injury or illness. To detect illicit drug abuse and the misuse of alcohol and other licit substances, the NRC has adopted a mandatory chemical testing protocol for these drugs. The rule provides for mandatory chemical testing prior to the initial granting of unescorted access or assignment to activities within the scope of the rule (§ 26.24(a)[1]). Mandatory chemical testing is to be conducted on a random basis to effectively detect and deter illicit substance abuse and misuse (§ 26.24(a)[2]). For-cause testing is to be conducted after an accident in which the contribution of employee performance cannot be ruled out or based on reasonable suspicion that an individual is intoxicated or demonstrates behavior indicative of substance abuse or other involvement with drugs (§ 26.24(a)[3]). Following a positive test for drug abuse, follow-up chemical testing will be used on an unannounced basis to verify abstention from the use of drugs or misuse of alcohol and other licit drugs (§ 26.24(a)[4]).

The NRC agrees that on-the-job impairment is a result of many complex factors, and that impairment is a complex phenomenon, depending on the cause of impairment, individual circumstances, and the job task at hand. The NRC recognizes that on-the-job impairment may result from substance abuse, psychological stress, or physical injury or ailment which can pose unacceptable safety risks, and the rule reflects this position. The NRC believes that trained, competent, reliable, and trustworthy workers are essential for the safe operation of nuclear power plants. The fitness-for-duty rule addresses the potential for worker impairment of any kind, including substance abuse that could affect the safe operation of nuclear power plants. In the assessment of a worker's application for access authorization, the background of the worker, psychological state, and criminal record are assessed. Similarly, any use of or involvement with illicit drugs, on or off duty, and the misuse of alcohol and other licit drugs provide evidence that the worker may not be fit for duty.

The NRC recognizes that even with a relatively high rate of random testing and with vigilance on the part of licensees to detect impairment or potential impairment in the workplace, the existence of drug problems within the workplace cannot be entirely eliminated. The undetected presence of drugs can be inferred from even a low positive test rate. However, the NRC concludes that the design features, redundancy of safety systems, and extensive training for unexpected equipment and personnel malfunctions provide reasonable assurance that the public health and safety is protected provided drug abuse continues to be aggressively addressed by the nuclear industry. The final rule provides reasonable measures to assure that nuclear power plant workers can safely, competently, and reliably perform their duties.

4.0 Scope of Rule

4.1 Summary of Comments

4.1.1 *Non-Power Reactors and other Licensees.* Several comments were received from universities and others involved with research reactors or other non-power reactors. The commenters stated that there is no need to extend coverage of the rule to these facilities because a drug-related problem has not been demonstrated to exist and that a relatively minor threat is posed by these facilities to the public safety. Unbearable costs and impracticality were also cited as arguments against inclusion of these facilities in the rule. A few comments were received from individuals involved with SNM handling, making the same general points. There were no comments

supportive of expanding coverage of the rule to facility types other than nuclear power reactors.

4.1.2 *Construction.* Comments were received from two licensees recommending that the language of the rule be changed to include plants during the construction phase.

4.1.3 *Types of Workers Covered.* The random testing provisions of the proposed rule would apply to all persons granted unescorted access to protected areas at operating nuclear power reactors. Most of the commenters who objected to this provision commented to the effect that including all individuals with unescorted access to protected areas is unnecessary, and asserted that many of these individuals, e.g., vendors, secretaries, clerks, and some engineering and management personnel, have no potential for precipitating or escalating a safety-related incident. As an alternative, it was suggested that only those licensee or contractor personnel with unescorted access to vital plant areas should be subject to random testing, since this more-limited group was viewed as including all individuals with the capacity to do significant, safety-related harm.

4.1.4 *Contractors.* Many commenters pointed out the lack of specificity concerning licensee vs. contractor responsibilities. Most of these, mainly from licensees, were of the opinion that the contractor should have full responsibility for a qualified fitness-for-duty program.

4.1.5 *Technical Support Center (TSC) and Emergency Operations Facility (EOF) Staff.* Several comments received on this issue stated that licensee or contractor personnel who may be required to respond to the TSC or EOF have been granted unescorted access and so are already covered under the rule and need not be specifically mentioned in § 26.3. Commenters questioned whether any non-licensee or non-contractor personnel involved with the TSC or EOF would have to be covered under the fitness-for-duty program.

4.1.6 *NRC Staff and NRC Representatives.* Many commenters contended that NRC staff should be subject to the same fitness-for-duty requirements, including random testing, as are licensee staff. Some thought that NRC representatives should be subject to these requirements also.

4.2 Summary of Responses

4.2.1 *Non-Power Reactors and other Licensees.* The NRC sees no reason at this time to extend coverage of the rule to other facility types. No modifications to the rule are required to satisfy the concerns addressed by the comments, because the rule is presently limited to nuclear power reactors. The NRC may consider extending the coverage of the rule at a future time.

4.2.2 *Construction.* The NRC agrees with the comments received that licensees holding construction permits should fall under the scope of this rule to the extent that a minimum program is provided. Wording indicating the provisions of the rule that pertain to construction sites has been added at Sections 26.2(b) and (c).

4.2.3 *Types of Workers Covered.* The NRC believes that the inclusion of all workers with unescorted access to the protected area within the scope of the rule is the proper response to the threat constituted by substance abuse. All such workers have the ability to carry in and distribute impairing substances. All such workers can engage in deliberate or accidental actions that can lead to challenges to safety systems or interfere with the ability of other workers to safely operate and maintain the plant. Although Federal requirements preempt State and local concerns in the area of radiological safety, in those states that support an on-site presence requiring unescorted access, the NRC may consider providing access to the chemical testing portions of the NRC's fitness-for-duty program if so requested by the individual states.

4.2.4 *Contractors.* The NRC believes that it is appropriate to hold licensees responsible for all workers to whom the licensee grants unescorted access, whether the workers are licensee employees or contractor or vendor personnel. The manner in which the licensee assures that contractor and vendor personnel are subject to the requirements of the fitness-for-duty program described in this part is left to licensee discretion, however. For example, nothing in the rule prohibits licensees from accepting the fitness-for-duty programs of their large contractors and vendors when those programs are effective and meet the requirements of this part. At their discretion, licensees may also choose to provide chemical testing and training for contractor and vendor personnel who are granted unescorted access to protected areas of a plant. This provision would likely be used when the contracting organizations have insufficient resources to support their own fitness-for-duty programs. The rule would require the licensee to provide a procedure to enable a contractor employee to appeal a positive alcohol or drug determination; this would not apply where the contractor is administering his own alcohol and drug testing. In recognition of the temporary relationship between licensees and most of their contractors and vendors, the NRC does not require the licensees to ensure that EAP services are provided to contract workers. However, nothing in the rule prohibits licensees from making these services available to contractor employees.

4.2.5 *Technical Support Center (TSC) and Emergency Operations Facility (EOF) Staff.* The NRC believes that it is particularly important that individuals who have TSC and EOF assignments related to nuclear power plant safety can be relied on to perform under the emergency conditions that would require them physically to report to the TSC or the EOF. To clarify the Commission's intentions in this matter, the words "physically report" have been added to § 26.2(a) of the rule. State and local representatives who may be present in licensee emergency facilities located outside the protected area and do not have responsibilities directly affecting reactor safety are not covered by the rule. Otherwise, these representatives would be covered by the licensee's program, or as an alternative, be covered by the NRC's program. Licensee employees, contractors, or vendor representatives who are unexpectedly called to licensee emergency facilities during an accident are also not covered by the rule as this group is ill defined and likely to be used only in supplementary capabilities.

4.2.6 *NRC Staff and NRC Representatives.* The NRC agrees with the commenters who asserted that NRC staff and representatives should also be subject to fitness-for-duty requirements. However, the NRC cannot allow the access of its employees to any part of the licensee's nuclear power facilities to be restricted. The NRC needs prompt, unfettered access to properly perform its regulatory duties and the proper performance of these duties requires public confidence that NRC employees not be intimidated or impeded in any way by those they are responsible for regulating. In general, the NRC expects that any NRC employee who requires unescorted access will be subject to the chemical testing provisions of the NRC's fitness-for-duty program. The Commission must reserve the right to obtain unescorted access for any of its employees.

The NRC also agrees that its contractors must be fit for duty and may cover certain of its contractors under the chemical testing provisions of the NRC plan. The Commission expects that NRC contractors who are granted unescorted access will either be subject to the

NRC's program, the licensee's program, or to a program that the NRC accepts as adequate. To be consistent with the Commission's intent, "representatives" has been deleted from § 26.2(a) of the rule, and replaced with "employees."

5.0 Chemical Testing

5.1 Summary of Comments

A large number of comments were received concerning the chemical testing provisions of the rule. These pertained primarily to the random testing provisions, but comments were also received concerning testing before granting unescorted access, for-cause testing, and follow-up testing.

The comments on random testing were directed both toward random testing, in general, and the proposed use of urinalysis as a testing technique, in particular. Comments were received that provided statements of general support or opposition to the random testing provisions. Comments were also received that raised questions about specific elements of the random testing program in the proposed rule.

5.1.1 *Opposition to Random Testing.* Opposition to random testing was expressed by numerous individuals; several unions including the Brotherhood of Carpenters and Joiners of America, the Utility Workers of America, and the International Brotherhood of Electrical Workers; over 200 union members as part of a letter writing campaign; one utility; and a few other organizations. While most explicitly supported the goal of a drug-free workplace, opposition to random testing as a means to achieve this goal was stated in the strongest terms.

A number of reasons were given for opposition to random testing. Many commenters were specifically opposed to random testing as an unwarranted invasion of privacy. Numerous commenters expressed the opinion that random testing is an infringement of Constitutional rights. Several questioned whether the extent of the drug problem in the nuclear industry warranted such drastic action.

Other reasons cited for opposition to random testing included:

- The view that random testing is ineffective in achieving the NRC's goals of deterrence and detection,
- Better techniques are available for deterring and detecting drug use,
- Random testing is excessively burdensome and expensive,
- Random testing is embarrassing and demeaning,
- Random testing creates morale problems and may thus lead to the loss of qualified and drug-free workers from the industry, and
- Inaccuracies in the testing process will lead to innocent people being accused and punished for wrong-doing.

5.1.2 *Support for Random Testing.* While many licensees viewed random testing as only one part of a comprehensive fitness-for-duty-program, most licensees and NUMARC expressed strong support for random testing as a major component of an effective program. This view was shared by several other organizations, such as contractors and vendors, as well as many individuals. NUMARC cited industry experience that the implementation of random testing programs has typically resulted in lower levels of drug problems.

Local No. 51 of the International Brotherhood of Electrical Workers expressed support for random testing when it is supplemented by behavioral observation. The Local reported that the affected workforce at the Illinois Power Company Clinton Nuclear Station is tested on a random basis each day and that this testing program, coupled with behavioral observation, has apparently proven to be a deterrent to drug abuse. This testing program was achieved through collective bargaining and is considered by the Local to be a valuable working practice. A check with the utility revealed that 100 percent of the workforce is given an unannounced test on an annual basis; and in addition, all persons are subject to random testing at a 20 percent rate. Since the rate of positive tests has significantly declined, the utility may plan to lower the rates.

5.1.3 *Alternatives to Random Testing.* A number of comments were received in response to the NRC's request for information on alternatives to random testing. The unions and affiliated locals and individuals, a number of other individuals, two licensees, and a few other organizations expressed the opinion that the goals of random testing could better be addressed through other methods. The majority of these commenters stated that a combination of behavioral observation, primarily on the part of the supervisor, and for-cause testing was both adequate and effective. Opinions were expressed that behavioral observation and for-cause testing have the advantages of not subjecting everyone to needless tests, dealing with fitness-for-duty problems in addition to drug abuse, and being more likely to stand up under review of the courts than random urinalysis. Most licensees also supported behavioral observation and for-cause testing, although not as a substitute for random testing.

A number of commenters suggested specific observational techniques including computer-assisted neurophysiological and neuropsychological tests, physical skills tests such as those used by law enforcement personnel, and Ocular Kinetics. Others suggested that the annual physical be used to screen for drug abuse, either through chemical testing or observation. Unannounced, random medical examinations were also proposed. Sacramento Municipal Utility District provided a detailed description of its program based on screening by trained medical personnel. This program was also cited by a few other commenters.

Several commenters proposed that drug awareness and health education were more effective deterrents. Other commenters stated that greater emphasis on rehabilitation would be more effective than random drug testing.

A few commenters suggested that pre-employment or pre-access drug screening was adequate. A few additional commenters preferred announced or periodic unannounced testing to random testing. Finally, a few commenters suggested that the NRC direct its attention to the underlying causes of drug abuse, such as the alleged poor work environment at nuclear power plants, rather than at detecting and punishing drug users.

5.1.4 *Specific Changes in Random Drug Testing Provisions.* Among the commenters who generally accepted the provision for random drug testing, a number of comments were received concerning the specific approach outlined in the proposed rule. Many of these comments, such as those having to do with drug types and cut-off levels, are summarized elsewhere. One major concern, however, had to do with the rate of testing to be required by the NRC.

Although the NRC had specifically requested comments on the preferred rate of testing, many commenters felt that the intention of the NRC was to require testing at a rate of 300 percent annually. Most of the comments received, therefore, addressed whether a 300 percent annual rate of testing should be imposed.

The 300 percent testing rate received very little support among those who otherwise supported random testing. NUMARC and most licensees stated that industry experience demonstrated that many fitness-for-duty programs had been successful with substantially lower rates of testing. Several commenters stated the opinion that a 300 percent testing rate would be unnecessarily

burdensome to the licensee in terms of costs, and to the individual in terms of repeated testing. A number of commenters questioned whether information from military experience that was apparently used in the NRC's decision to propose a 300 percent testing rate was appropriate to the nuclear power industry with its older and more stable workforce. Finally, one commenter questioned whether the testing laboratories could effectively handle the workload implied by a 300 percent testing rate.

Numerous commenters suggested alternatives to the 300 percent testing rate. Proposals ranged from a 5 percent per year rate to a 200 percent per year rate. However, NUMARC and most licensees proposed a 100 percent annual test rate for the random testing program. They further requested that the 100 percent rate be reevaluated based on the experience of utilities, and be reduced to a 25 percent rate if warranted by experience. A few commenters requested that the testing rate be left to the discretion of the individual licensee, because licensee management would be most knowledgeable about their particular situations.

A number of other testing strategies were proposed. One basic approach that was favored by several commenters was to require unannounced annual testing of all workers, augmented by random testing at a lower rate, such as 25 percent per year. Several other commenters suggested techniques for protecting individuals from being over tested. These included a request that a worker not be re-tested until all other workers have been tested, a request that tested workers be subjected to a lower rate of testing for the balance of the year, and that there be limits imposed on the maximum number of tests for a particular worker in a given year.

Commenters also expressed the opinion that workers of different types should be tested at different rates. A few commenters expressed the opinion that the testing rate should be relaxed for workers in non-safety critical jobs. Many commenters requested that licensees be allowed to establish different testing programs for their own, versus contractor or vendor, employees. Specifically, a number of utilities stated that treating all workers as one population would result in those workers who are permanently on-site being tested more frequently than those workers who are on-site for only part of the year. By having separate testing populations for licensee and contractor or vendor employees, the commenters felt that the burden of testing would be distributed more fairly.

Two inquiries were received concerning policy for those randomly selected individuals who are not on-site at the time they are selected. One commenter asked how they would be folded back into the testing population. The other stated the position that the workers should not be required to return to work solely for the drug test.

Several comments were received requesting changes in the definitions of random and unannounced tests contained in § 26.3.

5.2 Summary of Responses

The NRC is sensitive to the issues raised in opposition to random testing in general and to random urine testing in particular. Nevertheless, the NRC believes that there is sufficient evidence supporting the effectiveness of random testing in deterring and detecting substance abuse and that a carefully designed chemical testing program covering persons authorized for unescorted access to the protected area of nuclear power facilities is warranted at this time. As indicated below, in response to the sensitive issues of privacy and protection of individual rights, the NRC has taken great care to provide strict specimen collection procedures, chain-of-custody, laboratory certification, test confirmation, and confidentiality requirements within the rule. The NRC is convinced by evidence from the military and from licensees already implementing random testing procedures that random testing is an essential and effective component of the fitness-for-duty program. The NRC has designed the rule to minimize, to the extent possible, the expense and burden of the chemical testing component upon licensees, contractors, vendors, and upon their workers. Stringent quality assurance requirements are imposed upon the licensees, contractors, and vendors as well as upon the laboratories that will be conducting the chemical tests to ensure that test results will be accurate and that false positive results will be essentially eliminated.

Although the NRC believes that behavioral observation and for-cause testing comprise important elements of a substance abuse deterrence and prevention program, and has included them in its rule, it does not believe that, at present, these elements alone are sufficient to provide the level of deterrence and detection necessary. Nevertheless, the NRC appreciates the potential value of developing techniques in behavioral observation and detection of impairment through testing, and intends to monitor progress in these areas. It is prepared to modify the requirements of the fitness-for-duty testing program to incorporate such elements as they become viable, as long as the techniques address the reliability and trustworthiness issue of use as well as the safety issue of current impairment.

The NRC is sensitive to the importance of employee morale to plant safety, and has taken care to provide safeguards in the program to assure the fairness, uniformity, and accuracy of the random testing. The NRC also recognizes the value of health education and rehabilitation programs in assisting workers and in deterring substance abuse, and notes evidence that random testing programs have been found to be an effective incentive for workers to seek information and assistance. To this end, the NRC has included in the rule, as discussed below, requirements for a licensed physician to review positive test results prior to notification of the licensee, and is requiring that licensee workers have access to an employee assistance program designed to provide assessment, short-term counseling, referral services, and treatment and follow-up monitoring.

The NRC has considered a number of alternative rates and sampling procedures to address the many comments received. The NRC agrees that the high rates of testing needed in the military may not be as essential for the nuclear power industry, as long as adequate coverage and deterrence is assured. In this regard, the NRC notes that the Navy, using a 300 percent per year testing rate, observes about 5 percent positive tests. Commenters in the nuclear industry, with random testing programs, reported less than 1 percent positive tests, with a utility using a 100 percent per year rate reporting 0.5 percent positive. This appears to be reflective of a substantially different workforce population. The approaches considered were:

- Alternative A from the proposed rule, which sets the two goals that at least 90 percent of the workforce be tested and that the testing rate for the already-tested population during a year not be set lower than a rate equal to 30 percent of the workforce. The disadvantage of this alternative is its complexity of administration and the provision of a lesser deterrent during part of the year.
- Alternative B from the draft rule that requires testing at a rate equal to 300 percent of the workforce. The disadvantage of this alternative is the possible excessive disruption of work

activities and the testing of a few individuals at a very high rate which may impact morale. The cost of this rate may be excessive given the reported low number of positive tests for testing rates at 100 percent per year or lower in the nuclear industry.

• A method whereby each worker is randomly assigned a day during the next 365 days on which to be tested, and then is randomly reassigned to a day in the following 365-day period. The worker could be tested several times in one year, but is guaranteed at least one test per year. This allows for testing of the entire workforce during any 365-day period and reduces the testing rate in comparison to Alternative B (estimated rate: 200 percent). However, there is a possibility that more workers may be selected for testing on a given day than the licensee has a capacity to test. The disadvantage of this alternative is the need to select testing dates well in advance and the security problems which may result.

• A method whereby all workers are subjected to unannounced testing once during the year, and random testing at a low rate (e.g., 25 percent-50 percent) is also used during the year to assure ongoing deterrence.

• A method whereby random testing is conducted at a rate equal to approximately 100 percent of the workforce, resulting in about two-thirds of the workers being tested during the course of a given year. This is the alternative selected by the Commission and is reflected in the final rule.

While the NRC has considered a number of alternatives, several of the alternatives proposed by commenters were eliminated. The proposals for testing rates lower than 100 percent per year cannot currently be supported, although the NRC will consider reducing testing rates after several years based on positive experience in the industry. For the time being, however, the NRC believes that testing rates substantially below the 100 percent rate would not assure adequate deterrence. The NRC does not anticipate licensees experiencing significant problems in finding laboratory capacity to support rates in excess of 100 percent. Because of the need to assure an adequate minimum rate of testing, the NRC cannot leave the choice of a testing rate solely to the discretion of the individual licensee.

The proposal that workers not be retested until all other workers are tested and the proposal that there be a specified maximum number of times that workers are tested within a year cannot be supported because they would make the process non-random and would defeat some of the deterrent value of testing. Several of the above alternatives would have the effect of limiting the amount of retesting on particular individuals.

The NRC recognizes that vendor and contractor personnel could be subjected to lower rates of testing to the extent that they are not on-site for the entire year. The NRC believes that there are several strategies available to deal with the implied over-testing of licensee employees. The licensee can divide those being tested into discrete populations (e.g., employees and contractors, or even by contractor). The NRC expects that all categories of workers will be tested in accordance with the alternative rate and procedure selected for the final rule. The NRC will permit the licensee to sample within categories of workers, to sample randomly on at least a weekly basis among those currently on-site, or to employ some other method that satisfies the standards of the selected alternative for all categories of workers covered under this part.

The NRC does not believe that additional guidance is needed on how to deal with workers who are not on-site when they are randomly selected for testing. Current practice is to either test them immediately upon return to the site (with a supporting procedure that prevents disclosure of their selection), place them in a special pool of people to be randomly selected within a few weeks, or to return the person to the testing pool and select someone else. Usually, the licensee assures itself that there is a legitimate reason for the absence, and, if any patterns are evident an investigation is usually conducted along with for-cause tests. Current industry practice is considered adequate on this point.

6.0 Reliability of Test Results

6.1 Summary of Comments

The NRC received numerous comments pertaining to the reliability of test results. Several comments in this category expressed concern about the perceived high rate of false positive results and the possible consequences to workers. An official of the Utility Workers Union of America contended that immunoassay screening tests have false positive rates of 5 percent. A private individual cited a Human Relations Institute & Clinic's report claiming that laboratories using initial and confirmatory test procedures have had false positive rates ranging from 4.5 percent to 23.8 percent. Two commenters, a private individual, and an International Brotherhood of Electrical Workers (IBEW) union member asserted that testing laboratories in general have had false positive rates of 30 percent to 60 percent, respectively. The United Brotherhood of Carpenters and Joiners of America and two union locals, one of the IBEW and another of the Coalition of California Utility Workers, cited Center for Disease Control (CDC) study data from the early 1980s to claim that testing technologies are too inaccurate. One set of comments, mostly from the IBEW, wanted the NRC to ensure a 100 percent, or error-free, testing rate. Commenters attributed false positives to low cut-off levels, cross reactivity between drugs, and the varying levels of voided metabolites in the body associated with marijuana use. One commenter, the Utility Workers Union of America, thought that individuals who had received false positives should be awarded monetary compensation. Another commenter, the United Brotherhood of Carpenters and Joiners of America, contended that the EMIT 100 test used in initial screening had too high false negative rates.

Some commenters, mostly NUMARC and 39 licensees supporting the NUMARC comment, thought that the validity of the test results could be challenged either by the generation of true positives from use of over-the-counter drugs and other legal substances or by the mishandling of samples. Four other commenters (Florida Power and Light, the Oil, Chemical and Atomic Workers Union [OCAW], an IBEW union worker, and a private individual) identified the following as possible challenges to the validity of test results: mislabeling or misidentification of samples; use of improper sample collection techniques; inadequate safeguards against tampering; failure of laboratory equipment; passive inhalation of marijuana; time of day of the sample; and erroneous reading of test results. NUMARC and OCAW recommended adherence to chain-of-custody procedures, in general, while the Wisconsin Electric Power Company and the United Brotherhood of Carpenters and Joiners of America specifically recommended those procedures outlined in the HHS Guidelines. The Duquesne Light Company recommended that chain-of-custody procedures be followed at the site and in the laboratory. Houston Lighting and Power asked the NRC to prohibit personnel from working in the "Fitness-for-Duty Program" (that is, the testing program) who have relatives working at the site.

6.2 Summary of Responses

The NRC acknowledges the concerns regarding the rate of false positives and specimen collection and handling techniques, and recognizes that these concerns are based upon problems that existed several years ago when drug testing programs were being introduced. The Federal Aviation Administration, in their response to public comments on the same matter (53 FR 47032, November 21, 1988), provided a clear response that we find no reason to improve:

* * * In the early years of drug testing and analysis, laboratory security and analytical procedures had not reached today's level of sophistication. False-positive test results occur primarily in analysis of a specimen during an initial screening test, although contemporary screening tests, such as immunoassay tests, have become extremely accurate and approach 99 percent accuracy levels. Despite its increased accuracy, the initial screening test remains a less expensive test used only to yield a preliminary indication of the possible presence of drugs or drug metabolites. In order to ensure the integrity and accuracy of any test result, each positive initial screening test result must be confirmed using GC/MS analysis. The GC/MS confirmation test is an extremely accurate and sophisticated test and is virtually error-free when used in compliance with the DHHS guidelines * * * The Mandatory Testing Guidelines will provide a system of checks and balances during collection and analysis of specimens. This system ensures the integrity and accuracy of the tests using appropriate scientific methods and rigid chain-of-custody procedures * * * Since the mid-1980s, laboratories have become increasingly sophisticated in their analytical methods and chain-of-custody procedures. Many laboratories have compiled extensive records demonstrating scientific accuracy and protection of individual specimens. For example, CompuChem Laboratories, a major drug testing laboratory, has analyzed over 500,000 urine samples, conducting discrete testing for nine different drugs which resulted in nearly five million distinct analyses of these specimens, since 1980. CompuChem also has analyzed approximately 750,000 urine samples for the presence of two different drugs, resulting in nearly 1.5 million analyses of these specimens, pursuant to its contract with the military. None of the over six million analyses performed for DOT, the military, and other private and public entities has resulted in a false-positive test result.

In late 1987, a CompuChem clerical worker incorrectly labeled two samples that belonged to DOT employees. Within hours after the test results were questioned by the Medical Review Officer, CompuChem and the Medical Review Officer had identified and corrected the error. CompuChem was not satisfied with its prompt resolution of the error. As stated in its comment to the NPRM, CompuChem has instituted an additional system of review by CompuChem personnel and computer checks, to ensure that "* * * this one in a million error will not reoccur.

Another drug testing firm, PharmChem Laboratories, has conducted over eight million nonmilitary drug tests nationwide. In its statement to FAA during the public hearing held in San Francisco on June 9, 1988, PharmChem notes that several courts have determined that the GC/MS confirmation test is virtually 100 percent accurate, assuming that proper chain-of-custody procedures are followed * * *

The NRC has adopted the provisions of the HHS Guidelines with some modifications to further ensure the integrity and accuracy of test results using appropriate scientific methods and rigid chain-of-custody procedures at the site and in the testing laboratory. The confirmatory testing process also eliminates any false presumptive positive tests resulting from a cross-reacting drug detected during initial screening. As cross-reacting substances are generally prescription or over-the-counter medications, testing procedures in a licensee's fitness-for-duty program will include an inquiry on the individual's use of these medications.

Chain-of-custody procedures and a system of reviews, checks, and balances during collection and analysis of specimens outlined in the NRC Guidelines limit and prevent errors and possible subversions. To protect the worker from inappropriate sanction due to any errors in the testing process, cross-reacting substances, or legitimate medical use of controlled sustances, a Medical Review Officer (MRO) screens all presumed positive test results and may interview those individuals who have tested positive with the GC/MS confirmatory test. The MRO is trained in prescription and over-the-counter (OTC) drug interaction as well as the physical signs of illicit drug abuse. A comprehensive discussion of the MRO's responsibilities and a discussion of matters such as clinical signs of abuse are contained in the "Medical Review Officer Manual: A Guide to Evaluating Urine in Drug Analysis" (September 1988) published by the National Institute on Drug Abuse. The worker has an opportunity to identify any ingested licit, prescription, OTC drugs as well as certain food substances that may affect a test result. The chain-of-custody and collection procedures outlined in the NRC Guidelines, along with computer techniques of tracking specimens, limit the probability of mishandling, mislabeling, and misidentification of samples. The NRC Guidelines also outline procedures for the collection of samples to ensure the integrity of the samples and to limit opportunities for sample tampering. To further limit the possibility of subversion of the integrity of the testing process, the NRC Guidelines require licensees to carefully select persons responsible for administering the testing program based upon the highest standards for honesty and integrity and to implement measures appropriate to ensure that these standards are maintained. Background evaluations of testing program personnel would be conducted to verify the integrity of such individuals given the potential misuse of that position. Behavioral observation and periodic re-conduct of the background evaluations would assure continued integrity. Supervisory personnel and an individual's co-workers would be prohibited from performing as collection site personnel and consequently from being involved in the chain-of-custody process.

The NRC does not believe that "passive inhalation" of marijuana smoke will lead to false positives. Studies conducted to simulate conditions that result in passive inhalation have not accurately reflected conditions outside the laboratory often using artificially devised and extremely confined areas with poor ventilation, followed by immediate testing after prolonged exposure. The cut-off levels in the NRC Guidelines will be set sufficiently high to preclude the possibility of controversy due to chances that a positive test resulted from passive inhalation. The NRC notes that a trustworthiness question may be raised even in the case of passive inhalation. The only effect associated with the time of day of the sample is that urine samples collected earlier in the day contain higher concentrations of drugs or drug metabolites. Samples collected earlier in the day do not generate more false positives as initial positives are still confirmed with the GC/MS test. Erroneous reading of test results would be limited by chain-of-custody procedures and the system of reviews required of testing laboratories.

7.0 Training and Behavioral Observation

7.1 Summary of Comments

The NRC received numerous comments regarding the scope of training required of licensee, contractor, and vendor personnel granted unescorted access to protected areas. Most commenters concurred that training should be provided to all employees covered under the rule to ensure that they understand the licensee's fitness-for-duty program, their responsibilities, the consequences of substance abuse, and the availability of assistance through the Employee

Assistance Program (EAP). In accordance with NUMARC, many commenters supported the training of supervisory and managerial personnel in behavioral observation techniques and procedures for initiating appropriate corrective action, including referral of employees for medical assessment or counseling. However, a majority of commenters also expressed strong opposition to the proposed level of training required of non-supervisory personnel assigned escort duties (§ 26.22[b]).

The NRC also received a significant number of comments regarding the requirement that initial training of licensee personnel be completed prior to assignment of duties within the scope of this rule and within three months of initial supervisory assignment, as applicable (§§ 26.21[b] and 26.22[c]). Most of these commenters requested that the NRC revise the proposed rule to allow drug awareness and behavioral observation training to be completed within six months of initial supervisory assignment. Commenters also suggested that refresher training be completed every two years rather than annually.

7.2 Summary of Responses

The NRC has revised the proposed rule to clarify its intent that escort personnel are not required to receive training in supervisory responsibilities. The revised rule requires that all non-supervisory personnel assigned to escort duties must be familiar with techniques for recognizing drugs and indications of the use, sale, or possession of drugs; be familiar with techniques for recognizing aberrant behavior; and be knowledgeable of the proper procedures for reporting incidents of aberrant behavior to the appropriate management authorities.

The NRC received many comments opposing the required completion of drug awareness and behavioral observation training of supervisory and managerial personnel within three months of initial supervisory assignment. However, because of the critical position that supervisory and managerial personnel serve in detecting impaired workers, the NRC has determined that the current provision regarding supervisory training is necessary and will remain as stated in the rule.

The NRC has also determined that the provision requiring licensee personnel to receive annual refresher training in drug awareness and behavioral observation techniques will remain as stipulated in the proposed rule. Because supervisory personnel represent the first line of defense against fitness-for-duty problems, it is critical that they be trained to recognize these problems and handle them appropriately. Therefore, the NRC believes that the training of supervisory and managerial personnel in behavioral observation techniques will provide licensees with an invaluable tool for the detection and deterrence of drug-and alcohol-related impairment and for the detection of impairment from other causes. Because of the significant level of knowledge and training required to accurately detect subtle indications of drug or alcohol impairment and the critical need to identify drug and alcohol abusers before they compromise public safety, the NRC believes it is prudent to require supervisory training on an annual basis, or more frequently when necessary. In addition, the NRC will continue to require annual refresher training of all non-supervisory personnel to ensure that licensee and contractor employees understand the requirements of the licensee's fitness-for-duty program, are aware of their responsibilities, and, in the case of licensee employees, are aware of opportunities for assistance available through EAP services. NRC audits of licensee programs and interviews with contractor and licensee personnel have indicated a need for this level of refresher training.

8.0 For-Cause Testing

8.1 Summary of Comments

8.1.1 *Suitability of For-Cause Testing.* As summarized earlier, many commenters stated that they were in favor of for-cause testing in place of alternative testing methods such as random testing.

8.1.2 *Definition of Impairment.* Several commenters including NUMARC stated that the current definition of for-cause testing is too broad. Suggestions for improvement included replacing "is impaired" with "may be impaired" or "may have demonstrated aberrant behavior." Finally, commenters stated that most of the examples in paragraph 26.24(a)(3) of when for-cause testing should be required need better definition. Several examples were suggested.

8.1.3 *Testing Following an Accident.* Several commenters stated that requiring for-cause testing following an accident would inhibit root cause analysis of the accident. One commenter stated that for-cause testing should be required after a serious accident.

8.1.4 *Initiation of Testing.* Several commenters addressed who should be allowed to initiate for-cause testing. Several commenters stated that "impaired behavior" can only be determined by a physician or other health care professional. Others thought that a minimum of two management officials must document an employee's impairment. One commenter stated that for-cause testing should not be the result of a "discrete expression of concern by a nameless accuser."

8.2 Summary of Responses

The NRC agrees with the commenters that the definition of the circumstances in which "for-cause testing" is appropriate should be clarified. The definition provided in § 26.3 has been deleted and the language in § 26.24(a)(3) has been revised. The NRC does not agree that impaired behavior can only be determined by a physician or other health care professional. Supervisors are close to their workers and directly monitor worker performance, often on a daily basis. The NRC also does not agree that a minimum of two managers should be required to document a worker's impaired behavior. In some cases, the impaired behavior may be observed by only one manager during a task that cannot be easily repeated.

9.0 Sanctions

9.1 Summary of Comments

9.1.1 *Period of Denial of Access.* Sections 26.27(b)(2) and (b)(3) stipulate that, as a minimum, the first positive test confirmed by the Medical Review Officer shall result in immediate removal from access for at least 14 days and referral to an EAP for assessment and counseling. Any subsequent confirmed positive test would result in removal from unescorted access for a minimum of three years. A worker who is involved in the sale, use, or possession of illegal drugs while within the protected area of a power plant would be removed from covered activities for a minimum of five years. This section further specifies that the rule does not prohibit the licensee from taking more stringent actions.

This section prompted many and varied comments. Many licensee commenters including NUMARC argued that the entire § 26.27 should be deleted because licensee management has the responsibility to decide these issues. They believe that establishing sanctions is not within the Commission's statutory authority. Other licensees recommended that the rule should not prescribe any specific time periods for these events because each must be treated on a case-by-case basis. For instance, a licensee commented that some relatively minor situations do not require even fourteen days to assess the worker's drug usage,

determine a solution to the problem, and safely return the worker to unescorted access.

There was no particular consensus among those commenters who mentioned specific time periods for removal from access. Local No. 51 of the International Brotherhood of Electrical Workers recommended that a worker be suspended for five days after the first confirmed positive test and for ten days after the second. The System Council U–2 of the IBEW recommended discharge for six months after the second confirmed positive. Local No. 51 also believed that the three-year removal from access is too severe as it would almost certainly lead to dismissal. Permanent dismissal was recommended by Houston Lighting and Power even for the worker's first confirmed positive test. Carolina Power and Light believed that the 14-day requirement is adequate. Many licensees believed that they should have the option to undertake measures ranging from counseling through discharge following the first positive test result. They stress that they must have the flexibility to do whatever it takes to assure at least a chance at successful rehabilitation of the worker.

There was somewhat less variance in the comments on the appropriate response to a determination that a worker has been involved in the sale, use, or possession of illegal drugs within a protected area. Several licensees stated that the worker should be discharged in such circumstances. NUMARC recommended that the worker be permanently barred from access. Another licensee would discharge the employee but allow the person to be considered for rehire after three years.

9.1.2 *Follow-up Tests.* Section 26.27(b)(3) of the proposed rule [§ 26.27(b)(4) in the final rule] would require that workers whose access is reinstated "shall be given unannounced follow-up tests at least once every three months for three years after reemployment to verify continued abstinence from drugs." This requirement prompted a variety of responses. Various union representatives stated that this testing rate and duration would be "excessive, harsh, and punitive" and argued for less frequent testing over a shorter probation period. NUMARC recommended that workers regaining access be tested once every three months but for one year only. On the other side of the spectrum of views, Public Service Electric and Gas stated that the condition of such workers requires "close monitoring, tracking, and continued urine sampling." Rancho Seco's practice in such circumstances requires weekly urinalysis during the first quarter after return to work and monthly testing thereafter. (The length of the probation period was not mentioned.) A third set of commenters indicated that the frequency and duration of such follow-up tests need not be prescribed in the rule but should be left to the employer's determination.

9.2 Summary of Responses.

9.2.1 *Period of Denial of Access.* The Commission's intent in § 26.27 is that a worker who may pose a threat to safety be removed from safety-sensitive duties as long as he or she remains such a threat. These sanctions are not meant to serve as punishment for substance abuse. Thus, the section allows but does not mandate the permanent denial of unescorted access to protected areas in any of the enumerated drug-related events. The section also recognizes that the severity of threat to safety is a complex matter. Obviously, a long-term heroin addict with an expensive habit would likely be a far more serious threat than a recreational marijuana user. Yet, an effective fitness-for-duty program must be prepared to deal with both types of problems.

It is the NRC's belief that § 26.27(b)(2) includes an appropriate mix of flexibility and stringency. The 14-day period seems reasonable in that, in almost all cases, it would take at least that long to diagnose a worker's problem, determine a solution, and assure that the problem is addressed before the worker can again be granted access; this may, in some cases, be limited to counseling. Also, the NRC believes that 14 days is needed to conclude that the first confirmed positive test may have resulted from behavior that does not in fact pose a serious safety threat. This minimum period is not meant to constitute punishment. Instead, this period is intended to ensure an adequate time for assessment of the worker's condition and requirements. The NRC does not take a position on whether a worker in this situation should be denied unescorted access longer than 14 days. That is to be decided by the licensee.

Removal from unescorted access for a minimum of three years after a second confirmed positive test is, on the other hand, quite a stringent requirement. Some commenters noted that dismissal may occur in such cases. The NRC believes that this measure is appropriate, however, in light of this rule's goal of assuring that workers are not impaired due to substance abuse. A second positive test would indicate that the person is most likely not able to stop using the substance in question and could, therefore, pose a threat to safety. The severity of a three-year loss of unescorted access may also provide an incentive for employees to voluntarily enter into rehabilitation programs when they realize the seriousness of the substance abuse problem.

Section 26.27(b)(3) also appears to be well suited to the rule's goal. The tenor of most comments on this section favored more stringent measures than the section would require, and the NRC wishes these commenters to note that the five-year period is intended to be only the minimum removal from unescorted access necessary to protect public health and safety. The five-year period should operate as both a deterrent to the proscribed activities and as a measure that may in fact result in permanent denial of access in most cases where involvement in illegal drugs is detected in protected areas.

9.2.2 *Follow-up Tests.* The NRC recognizes the need to adjust the frequency of follow-up testing as required in § 26.27(b)(4). Research indicates that recidivism is most likely during the first 90 days following treatment (Hubbard and Marsden' 1986; Rounsaville. 1986). Most relapses to substance use will take place during that first 90-day period. If a person can remain substance-free during that period, he or she will have a chance to continue to be abstinent.

In light of this research, the Commission has amended this section. Rather than requiring a uniform frequency of testing for the entire three-year probation period, the heightened potential for recidivism during the early stages of that period should be recognized with a rate of testing more frequent than once every three months.

As amended, this section requires that workers whose access is reinstated be given unannounced follow-up tests at least once every month during the first four months of restored access. During the next two years and eight months, the worker should be tested at least once every three months to verify continued abstinence. As compared to the proposed rule's requirement, the higher testing rate during the first four months would provide the worker with an increased incentive to remain abstinent as well as create an increased probability of detecting any resumption of substance use that may occur. Thereafter, the lower testing rate would be less onerous for the worker while still providing added assurance that resumption of substance use would be detected.

10.0 Impairment From Other Causes

10.1 Summary of Comments

A number of commenters discussed issues pertaining to impairment from causes other than workers' use of illegal drugs.

10.1.1 *Identified Additional Sources of Impairment.* Workers' use of substances was mentioned most often in these comments, especially the use of alcohol, prescription medications, and over-the-counter medications; the use of caffeine was also mentioned. Comments were also made about the following specific sources of worker impairment: (1) Emotional and mental stress in general and stress specifically related to poor attitudes, poor morale, and family problems; (2) fatigue, including fatigue caused by mandatory long hours of duty, rotating shifts, and workers working shifts incompatible with their biological clocks; (3) illness, including allergies; and (4) physical and physiological impairments. One commenter noted that illnesses, particularly colds and flu, are major causes of impairment because both the illness and the medication a worker takes to treat the illness can cause impairment. With regards to fatigue, one commenter objected to the proposed rule because, under the rule, it was his interpretation that workers may be disciplined and possibly terminated due to fatigue caused by work schedules and overtime.

A number of commenters did not specifically address any one of these sources of impairment, but expressed one or more of the following general concerns: (1) The rule should be expanded to address several or all of these potential causes of impairment, regardless of the source of the impairment; (2) it is inappropriate for the rule to focus on illegal drug use and not to also address, in detail, the use of legal drugs, alcohol, or both; and (3) the rule requires licensees to address impairment from sources other than illegal drug use and to provide reasonable assurance that on-duty workers are not impaired from the use of any substance, but it provides no guidelines or direction towards this end.

Some commenters noted that urine testing is an inadequate means of detecting impairment caused by many of these factors, and thought that specific tests for impairment, medical clarification exams, or supervisors' observations should be used to detect impairment.

10.1.2 *Legal Drugs.* Some commenters thought that the rule should not address legal drugs. One commenter stated that impairment should not be addressed and that the concern should be limited to illegal drug use. Another commenter thought that the language of the rule should be changed to state that the goal of the rule is to achieve a workplace free of *illegal drugs* and their effects rather than a "drug-free workplace." This commenter also noted that this change should not preclude a licensee from prohibiting on-site use of alcohol. Several commenters stated that expanding the rule to address legal drugs would raise substantial legal concerns (e.g., making the use of legal drugs illegal, forcing a violation of physician/patient confidences) and one commenter thought that these concerns merely highlight the fact that any drug testing is an affront to personal liberty.

NUMARC stated that prescription drugs should be addressed only generally; workers should be required to notify their supervisors of intended use of prescription drugs and care should be taken in response to positive tests that occur as a result of prescription drug use. If prescription drugs are included in the testing program, the response to positive test results should be based on medical advice and workers must not be penalized unless they are abusing the legal/prescription drug. This position was strongly supported, with about half of those commenters who discussed legal drugs supporting the NUMARC position.

Several commenters stated that only the drugs listed in the HHS Guidelines should be the basis for industry testing. The addition of drugs beyond those specified in the HHS Guidelines would create a conflict with HHS restrictions. Further, a number of commenters were concerned that the procedures specifying how licensees are to identify additional drugs and incorporate them into their programs would defeat the goal of establishing uniformity. Commenters also thought that these procedures were unworkable, burdensome, and open to legal challenges.

A number of commenters stated that the rule should not be expanded to address legal drugs, and that workers should not be denied the use of medications necessary or beneficial to their health and well-being. Several commenters stated that regulation on prescription drugs is outside of the appropriate scope of NRC regulations and that such decisions should be made by physicians and on an individual basis. Other commenters thought that testing for legal drugs is unnecessary, but workers should report the use of those drugs either to their supervisors or to the medical department for an individual decision to be made about what actions should be taken to ensure against on-the-job impairment. One commenter indicated that the prescribing physician could be consulted when making this determination.

Other commenters stated that it was appropriate to expand the testing program to include legal drugs that may cause impairment. Some of these commenters want the rule to specifically state this, while others want the rule to address the testing protocol for these drugs in detail, as has been done for the classes of drugs for which the rule does require testing. The following drugs or drug classes were identified by various commenters as warranting special concern: barbiturates, benzodiazepine, methaqualone, methadone, and propoxyphene. For some of these drugs and drug classes, cut-off levels were proposed.

Commenters also pointed out that some of the classes of drugs currently tested for include drugs that can be used for legitimate medical reasons without creating significant impairment, and the rule should be expanded to ensure such legitimate use of these drugs is protected. Several commenters stated that requiring workers to report the use of prescription drugs to their supervisors adequately addressed the concerns surrounding the use of legal drugs.

10.1.3 *Alcohol.* Many commenters made statements about whether or not alcohol should be added to the rule. The majority of these commenters, about 60 percent, stated that the rule should be expanded to address alcohol, but that details of how alcohol will be addressed should be published for public comment before the changes are implemented. These commenters include NUMARC, a number of commenters who stated that they support the position stated by NUMARC, and a number of commenters who made this statement without linking it to NUMARC. About 25 percent of the commenters addressing this issue stated that alcohol should be addressed in the rule without such a qualification. About 15 percent of the commenters who addressed this issue stated that alcohol should not be addressed in the rule. Other commenters expressed the concern that the extent to which alcohol is addressed in the rule should not make implementation an insurmountable burden.

The following reasons were given for delaying implementation of an alcohol rule: (1) Time should be allowed for the industry to study and develop additional suitable and effective programs to handle alcohol-related problems, much the same as has been provided for drug program development, and (2) prior to final rulemaking, the details of the

alcohol requirements should be made available for public comment.

The following reasons were given for including alcohol in the rule: (1) Alcohol use and misuse is prevalent, (2) alcohol use can lead to on-duty impairment, (3) alcohol misuse creates fitness-for-duty problems comparable to and perhaps more substantial than the problems caused by illegal drug use, and (4) an NRC regulation requiring testing for alcohol would lend support to established programs.

The following reasons were given for excluding alcohol from the rule: (1) Programs already in place and guidance being produced by Edison Electric Institute (EEI) effectively deal with alcohol-related problems, making additional guidance or regulations unnecessary; (2) if additional prescriptive detail is provided, and if that guidance conflicts with established programs, the rule could result in a less effective approach to dealing with alcohol-related fitness-for-duty problems.

Many specific recommendations were made about the desirable characteristics of an alcohol testing program. A number of commenters recommended using breath tests for blood alcohol concentrations (BACs), although some commenters said that blood tests are more accurate and should therefore be used. Most commenters stated that alcohol should be treated in a manner similar to other drugs, and that testing for alcohol and other drugs should be done on the same occasions. NUMARC, along with about 35 other commenters, stated that tests for alcohol should be done on a random basis, as compared to three commenters who stated that alcohol should only be included in for-cause tests. A few commenters thought that alcohol testing as part of pre-access or preemployment screening was unnecessary. Several commenters addressed BAC cut-off levels by stating the level they recommended, stating the level they were currently using, or urging the NRC to establish a cut-off level. Recommended or currently used cut-off levels ranged from 0.04 percent to 0.10 percent, with the vast majority of commenters citing the 0.04 percent cut-off level. One licensee requested the NRC to establish the 0.04 percent cut-off level, but stated that if the NRC does not establish this level, they would use the 0.10 percent BAC cut-off level used in their local state motor vehicle codes. With regards to sanctions in the event of a violation of alcohol policy, commenters expressed both the opinion that it is appropriate to regard a positive alcohol test the same as a positive drug test, and the opinion that sanctions for violations of the alcohol policy should differ from sanctions for violation of the drug policy and should be left to the discretion of the licensee.

One commenter recommended a rule requiring a period of pre-work abstinence from drinking, such as the eight-hour rule used in the aviation industry.

10.2 Summary of Responses

The NRC agrees that the possible sources of impairment identified by these commenters constitute important fitness-for-duty concerns that should be addressed in licensees' programs. Further, the NRC believes that the rule does address these issues, in that the rule requires licensees to provide reasonable assurance that workers are not impaired from any cause and requires licensees to make EAPs available to workers to assist them with these types of problems.

10.2.1 *Additional Sources of Impairment Not Warranting Action at This Time.* The NRC does not believe that the health and safety of the public is best served by the NRC providing, at this time, additional prescriptive regulations regarding emotional and mental stress, fatigue, illness, and physical and physiological impairments. The NRC believes that there are a number of ways of effectively addressing these problems, that often the approach used must be tailored to the specific case at hand, and that sound management practices, which are consistent with the licensee's management style, can be expected to be more fruitful than would detailed prescriptive regulations.

Additional Sources of Impairment Warranting Action at This Time

The NRC agrees with the commenters who stated that the rule should be expanded to address impairment that is caused by workers' use of alcohol and legal drugs. The NRC believes that these are especially significant areas of concern because of the negative effects of alcohol and prescription sedatives on vigilance and judgment, which are important components of many jobs within protected areas. The NRC also believes that there is often a relationship between illegal drug abuse and the abuse and misuse of legal drugs and alcohol. The distinction between some types of medication use and drug abuse is not absolute. All use of prescription and over-the-counter drugs lies somewhere in a spectrum that has responsible safe use at one end, dangerous abuse at the other end, and practices such as irresponsible misuse and accidental misuse somewhere in the middle. For these reasons, the NRC believes that a licensee's policies regarding workers' use of legal drugs and alcohol is as important for ensuring public health and safety as the licensee's policy regarding illegal drug use.

The nexus between illegal drug abuse and the abuse or misuse of legal drugs and alcohol makes it difficult to separate these issues. For example, in some cases the proposed rule addresses classes of drugs that are both abused illegally and used in legal medications (e.g., opiates and amphetamines). Therefore, within a drug testing program adhering to the proposed rule, an overlap between illegal and legal drugs already exists.

Additionally, many of the issues that must be resolved when addressing each of these areas are very similar. For example, if chemical testing is to be used to detect the use of one or more legal drug(s) or alcohol, then the issues pertaining to the testing protocol that must be addressed when testing for illegal drugs—such as chain of custody, establishing cut-off levels, laboratory quality assurance—must all be addressed. Further, all of these issues should be addressed because individual workers may have closely-related substance abuse problems involving illegal drugs, legal drugs, and/or alcohol. Effectively detecting and deterring the abuse of some substances (illegal drugs) while failing to detect and deter the abuse or misuse of others (legal drugs, alcohol, or both) may result in some workers who have drug problems merely substituting one impairing drug with another rather than giving up the unacceptable use of any drugs. This close tie between illegal drug abuse as a fitness-for-duty concern and legal drugs and alcohol as fitness-for-duty concerns, along with the significance of these issues, warrants the NRC addressing all of these issues in a fitness-for-duty rule.

The NRC does not agree that it is beneficial to wait until licensees have studied these problems and attempted to develop their own solutions before taking action. The NRC believes that, as was the case when the NRC delayed rulemaking regarding illegal drug use, such a practice may contribute to inconsistent policies in the industry and that it is possible that some policies will be developed that prove to be inadequate. Further, such a waiting period would result in an unacceptable delay in the implementation of important components of the NRC's fitness-for-duty rule.

10.2.2 *Legal Drugs.* The NRC does not think that it is appropriate to publish

detailed regulations concerning legal medications at this time. The NRC acknowledges that the task of establishing the panel of drugs for which testing is warranted, and the appropriate testing protocols to be used when performing those tests, is an important and difficult task that warrants careful consideration. Further, the NRC believes that all of the approaches recommended by commenters regarding the regulation of workers' use of legal drugs may prove unacceptable. Some of the recommended approaches can be expected to provide inadequate assurance that a worker's use of legal drugs does not result in on-duty impairment. Other approaches may prove to be unnecessarily intrusive. For example, it may be unnecessary for workers to report to a supervisor or Medical Review Officer their use or intended use of some prescription drugs.

The NRC believes that requiring workers to report to the Medical Review Officer their use or intended use of some types of drugs is essential, however, and should be considered by licensees. However, the NRC believes that defining these drugs in terms such as "all prescription drugs" or "all drugs that may cause impairment" may be a poor method of developing such a list. There may be over-the-counter drugs, such as over-the-counter stimulants and sedatives, that have significant potential for causing on-duty impairment and thus warrant being reported. Conversely, there may be prescription drugs that have very little potential for causing impairment and do not warrant being reported. Specific policies could be produced that would eliminate the need for workers to report their use of these drugs. For example, it may be possible to assure that some drugs do not create significant problems simply by providing guidance to workers about when the drugs can be used or about the maximum doses of the drugs that can be used by on-duty workers. The development of such guidance could simplify licensees' fitness-for-duty programs, promote consistency throughout the industry, and reduce the intrusive nature of the fitness-for-duty programs. However, the NRC believes that such guidance should be developed by the industry. Input from the medical community would be especially valuable in this area and should be sought. Should timely progress not be made in this area, the NRC may institute additional rulemaking.

The rule has been modified to require licensees to educate workers about the effects legal drugs may have on job performance. Also, in line with comments, the NRC accepts that chemical testing for some legal drugs is appropriate, however, whether to test for these drugs, such as barbiturates and benzodiazepines, is left to the discretion of each licensee. The Commission has asked the staff to explore with the Secretary, DHHS, the addition of these drugs to the required testing panel.

10.2.3. *Alcohol.* The NRC believes that alcohol is a fitness-for-duty concern. The NRC believes that no on-duty alcohol consumption should be permitted, and that conducting breath tests to determine workers' BACs is a necessary step towards detecting and deterring any on-duty use or any unacceptable off-duty use of alcohol.

Breath tests, when conducted following the protocols in the NRC "Guidelines for Nuclear Power Plant Drug and Alcohol Testing Programs" (Appendix A to Part 26), provide relatively accurate and reliable measures of BACs, and are sufficient for all alcohol tests. Workers should have the right to have further confirmatory tests performed at their request. Because of the improved accuracy obtained when using blood samples, further confirmatory tests will be performed using blood samples analyzed with gas chromatographic methods.

The NRC believes that the scientific literature strongly demonstrates that BACs can be correlated with impairment, and that a BAC cut-off level of 0.04 percent is appropriate. This cut-off level is low enough to provide reasonable assurance that alcohol-caused impairment will be detected when breath tests are performed, and high enough to eliminate practical and technological problems associated with very low cut-off levels. The NRC therefore requires that blood alcohol concentration cut-off levels be set at 0.04 percent. Licensees have the general responsibility for evaluating the fitness of their personnel whether or not some specified limit is indicated for either drugs or alcohol. Licensees may establish lower cut-off levels, but should recognize that there are practical problems associated with a zero or near-zero cut-off level for alcohol, and should consider the potential impacts of these problems carefully before using very low cut-off levels.

The NRC recognizes the value of a required period of abstinence from drinking that should precede all scheduled tours of work. The NRC therefore is requiring licensees to include an abstinence period of at least 5 hours in their fitness-for-duty programs.

The NRC does not agree with those commenters who state that chemical tests for on-duty alcohol-caused impairment need only be performed on certain drug testing occasions, such as when for-cause testing is performed. The NRC believes that licensees should not indicate to workers that alcohol use that results in on-duty impairment is of less concern than is illicit drug use. Further, the NRC believes that any use of alcohol that results in on-duty impairment poses a significant potential threat to public health and safety.

Finally, the NRC agrees with comments that state that it would be easy for a worker to pass an announced test for alcohol misuse, such as a pre-employment or pre-access authorization screening. However, this is true for many illicit drugs that, like alcohol, are eliminated from the body relatively quickly. As is the case when testing for these illegal drugs, detection of rule violations may be rare, as workers need only abstain for a reasonable period prior to the test to be assured of passing the test. However, it is also very likely that those who are detected through such tests will have a very substantial problem that must be addressed. Some licensees who currently include tests for alcohol in their preemployment screening process have discovered several alcohol abusers who would have gone undetected without the screening process. For these reasons, the NRC requires that chemical tests for the misuse of alcohol be conducted whenever tests for illegal substance abuse are performed. Furthermore, to assure deterrence against "lunch time drinking" the rule will require that random testing be conducted at various times during the day.

With regards to sanctions related to alcohol in the final rule, the NRC agrees that it may not be essential that the actions taken to address alcohol misuse be identical to the actions taken to address illegal substance abuse. However, the NRC does believe that it is essential that licensees test for the misuse of alcohol and that detected impaired workers are removed from duty. Further, sanctions must be adequately severe to deter drinking practices that result in on-duty impairment, and severe enough, as compared to the sanctions associated with illegal drug use, to ensure that workers who abuse illegal drugs are not encouraged to merely switch from a pattern of unacceptable drug taking activity to a pattern of unacceptable alcohol consumption. One way of doing this is to take actions in the event of a violation of the alcohol policy that are

the same as, or similar to, the actions taken when the illicit drug policy is violated. In the absence of such actions, an effective program must provide assurance that a high level of deterrence is present and that workers who are impaired as a result of alcohol misuse are removed from duty.

11.0 Confidentiality of Test Results

11.1 Summary of Comments

A number of commenters were concerned about the confidentiality of test results and the potential impact of the rule on the privacy of workers. There was concern that test results might be inappropriately released to the detriment of workers. A number of specific suggestions were made to protect workers' rights.

11.1.1 *Confidentiality of Results.* One commenter favored identifying samples by a number coded to an individual worker rather than by name. Other commenters believed that there should be a protocol defining which licensee's workers should have access to fitness-for-duty records at various stages of the testing process. Several commenters expressed the view that test results should not be releasable to licensees or contractors under 10 CFR 26.27(b) without the written approval of the affected worker. One commenter proposed that all medical personnel involved in the fitness-for-duty process adhere to the American Occupational Medical Association's (AOMA's) "Code of Ethical Conduct for Physicians Providing Occupational Medical Services," and the AOMA "Ethical Guidelines for Drug Screening in the Workplace."

11.1.2 *Use of Samples for Other Purposes.* A number of commenters were also concerned that specimens taken from workers would be used for purposes beyond the scope of the proposed fitness-for-duty rules and suggested that language be added to the regulations limiting use of the samples to designated purposes.

11.1.3 *Tests Conducted by the Licensee.* The proposed rule (10 CFR 26.24[d]) would allow licensees to conduct preliminary tests of a sample before forwarding it to a laboratory. Several commenters were concerned that results of such preliminary tests would be inappropriately disclosed and acted upon prior to confirmation by the contract laboratory. They proposed that access to the results of such preliminary tests should be strictly limited, perhaps to the licensee's laboratory staff only.

11.1.4 *Confidentiality for Employee Assistance Programs.* One commenter noted the lack of specific confidentiality requirements in the proposed (§ 26.25) on employee assistance programs and stated that such protections were necessary for the programs to be successful. Another commenter stated that the term "safety considerations," as used in this section, should be defined. A commenter also requested that language be added that employee assistance program EAP counselors would notify management when a belief exists that any worker's condition (self-referred or not) may constitute a hazard to himself or others.

11.1.5 *Access to Records.* Several commenters suggested that access to the results of chemical testing should be limited to the greatest extent possible, especially given the potential damage to a worker from disclosure of false positive results. In particular, many commenters believed that test results should not be released to law enforcement agencies.

There were a number of comments concerning access to fitness-for-duty records by NRC employees and representatives. Several commenters expressed the view that the NRC has no need for access to individual names and that if such information were provided it might be inappropriately disclosed or made available to the public. It was noted that licensees are expressly directed not to include the names of individuals under the proposed reporting requirements to NRC (§ 26.73[a][3]), but that NRC is eligible to receive names under proposed § 26.29(b).

Two commenters suggested that the Protection of Information (§ 26.29) include references to contractors and vendors as well as licensees. They further suggested that the reference to employment decisions be replaced by access decisions. Another commenter raised the question of whether contractors as well as licensees should be able to obtain fitness-for-duty information under the proposed regulation at § 26.29(b). An additional commenter suggested that release of fitness-for-duty information under a court order be added to the list of permitted disclosures under § 26.29(b).

11.2 Summary of Responses

11.2.1 *Confidentiality of Results.* The NRC believes that further requirements for the protection of worker records at the testing laboratory beyond the requirements of the NRC Guidelines are not needed at this time. Section 3.1 of the Guidelines contains specific protections for such records.

The NRC concurs in the comment that information on a worker denied unescorted access or removed from his position under a fitness-for-duty program shall be provided to licensees and contractors subject to this part but only upon a written release by the affected worker. Appropriate language has been added to § 26.27(a). The effect of the language is that if the worker elects not to provide such a release to the hiring licensee or contractor, the worker would be denied unescorted access to protected areas.

The comment that Medical Review Officers subscribe to the AOMA Code of Ethical Conduct and their ethical guidelines for drug screening in the workplace has merit. The NRC will continue to study this suggestion. For purposes of the present rulemaking, however, the NRC is satisfied that the statement of qualifications for Medical Review Officers in § 2.9(b) of the NRC Guidelines is adequate and sufficient.

11.2.2 *Use of Samples for Other Purposes.* The NRC believes that provisions in the rule limiting use of laboratory results to the purpose and scope of the rule are adequate. The protections afforded by the NRC Guidelines and § 26.29(b) are deemed to be sufficient. Specifically, § 2.1(d) of the NRC Testing Guidelines requires that specimens collected under Part 26 may only be designated or approved for testing as described in Part 26, and shall not be used to conduct any other analysis or test without the permission of the tested individual. Moreover, there should be no incentive for employers to disclose the information to unauthorized persons because of the possibilily of liability related to such disclosure.

11.2.3 *Tests Conducted by the Licensee.* The NRC concurs that there is a potential for abuse of positive test results from preliminary tests conducted by the licensee. These preliminary tests do not have the accuracy of laboratory-conducted confirmatory tests. Consequently, the final rule limits access to the preliminary test results to the licensee's testing personnel.

11.2.4 *Confidentiality for Employee Assistance Programs.* The EAP requirement at § 26.25 specifies that such programs are to provide confidential assistance except where safety considerations must prevail. The NRC believes that the plain meaning of these terms is sufficient for this rulemaking and that further clarification in the rule is not required. The NRC concurs in the suggestion that employee assistance program counselors notify management when there is a reasonable belief that any worker's condition may constitute a hazard to himself or herself or others, and the rule's language has been clarified.

11.2.5 *Access to Records.* The NRC has elected to retain the provisions on entities entitled to access to laboratory records as proposed in § 26.29(b) with the exception that release of the information under a court order is added. The NRC does not anticipate requesting the results of laboratory tests correlated to individual names. Nevertheless, the NRC wishes to reserve the right to have access to specific results when needed for particular situations involving safety and investigative matters such as malfeasance in the administration or management of the fitness-for-duty program. The NRC also has decided to retain the provision providing access to appropriate law enforcement officials, but has added the provision that such officials must be under court order. It is noted that there is no requirement to routinely provide such officials with laboratory results. Moreover, it is unlikely that such results would be requested because the officials would have no prior knowledge of the results of laboratory tests.

The NRC concurs in the comment that contractors within the scope of the rulemaking should be included in the disclosure and access provisions of § 26.29(b) and the final rule reflects this addition. The reference to employment decisions in the proposed rule has been replaced by access decisions.

12.0 Employee Assistance Programs

12.1 Summary of Comments

The NRC received a significant number of comments from licensees regarding employee assistance programs. The majority of commenters agreed that employee assistance programs services are an effective method of combatting the broad spectrum fitness-for-duty problems. However, most of the commenters specified that under the proposed rule the scope of licensee employee assistance program services should be limited to regular, full-time licensee personnel; contractor or vendor personnel should not be covered. Several other commenters indicated that employee assistance program services should not be regulated by the NRC rule in any manner, and would be better addressed by the licensees themselves.

12.2 Summary of Responses

The NRC believes that employee assistance program services provide a valuable tool in combatting fitness-for-duty problems in the nuclear power industry. Therefore, as currently stipulated in the rule, it is the responsibility of each licensee to ensure that all licensee personnel have access to employee assistance programs services and that contractor employee assistance programs meet the criteria of the licensee's employee assistance programs. The NRC has also noted that supervisory personnel should not refer employees directly to counseling or treatment. Rather, supervisory personnel should refer employees to an employee assistance program counselor for assistance and further evaluation and referral.

13.0 Importance of Health and Human Services Guidelines

13.1 Summary of Comments

13.1.1 *Proposed Alternatives to the HHS Guidelines.* Several commenters suggested that an alternative to the HHS Guidelines is the College of American Pathologists (CAP) Forensic Urine Drug Testing (FUDT) program. The commenters contend that the CAP FUDT program is as equally rigorous as the HHS Guidelines but better suited to licensee's needs because: (1) It has an educational component for laboratories, (2) it has accredited 25 laboratories as of October 11, 1988, whereas NIDA has accredited none, (3) the CAP FUDT program allows laboratories to test for additional drugs and at other cut-off levels than those specified in the HHS Guidelines, and (4) the CAP FUDT program does not require approval from the HHS Secretary.

One commenter suggested that an alternative to the HHS Guidelines is the "AFL–CIO Guide for Drug and Alcohol Testing on the Job." Several commenters pointed out that stringent quality controls are required of testing laboratories under state programs; two commenters stated that New York State had a stringent laboratory certification program.

13.1.2 *Applicability of HHS Guidelines to the Nuclear Power Industry.* A few commenters indicated that the HHS Guidelines should be adopted by the NRC in their entirety. The large majority of commenters stated that, although the HHS Guidelines provide many excellent procedures for ensuring the quality of drug testing programs, the HHS Guidelines contain terminology and provisions that are inappropriate for application to the nuclear power industry. The inappropriate terminology and provisions noted by the commenters include (1) references to "agencies," to Pub. L. 100–71, to the Privacy Act, and to the HHS Secretary; (2) limitations in the panel of drugs for which certified laboratories can test; (3) cut-off level specifications defined for screening and confirmatory tests; (4) requirements that a licensed physician, as a Medical Review Officer, review all test results; (5) the conflict with on-site testing created by the requirement that all testing be done by certified laboratories; (6) laboratory certification procedures; and (7) limitations on splitting specimen samples. To ensure that the HHS Guidelines are appropriately adapted to the proposed rule, many commenters recommended that the pertinent sections of the HHS Guidelines be incorporated into the rule itself.

13.1.3 *Limitations in the Panel of Drugs for Which Certified Laboratories Can Test.* A number of commenters specifically supported the intention and value of establishing uniformity across licensees in the panel of drugs, with a smaller number supporting a more flexible approach that allows licensees discretion to deal with local variability in drug use.

A number of commenters objected to the procedures specifying how licensees are to identify additional illegal drugs and incorporate them into their programs, on the grounds that these mechanisms defeat the purpose of uniformity, are unworkable, are burdensome, and open licensees to legal challenges. Some of these same commenters, along with others, recommended that the HHS-specified panel of drugs be expanded to include (for example) alcohol, methadone, barbiturates, benzodiazepine, propoxyphene, methaqualone, and prescription and over-the-counter drugs. Comments made at the public meeting expressed concern about the potential for intrusion into personal medical information if the panel of drugs is not strictly specified and limited.

13.1.4 *Cut-off Levels Defined for Screening and Confirmatory Tests.* A substantial number of comments were received on the cut-off levels for screening and confirmatory tests, many suggesting specific cut-off levels for particular drugs. An important disagreement among commenters centered around the issue of uniformity in cut-off levels. Some commenters recommended that standard cut-off levels be established and applied by all licensees in order to minimize inconsistency across licensees, maximize the defensibility of the cut-off levels, and avoid conflict with the certified laboratory testing procedures. These commenters thought that discretionary cut-off levels were unworkable because they would be challenged in court and were inconsistent with certified laboratory procedures specified in the HHS

Guidelines. Among these commenters, some supported the existing HHS cut-off levels and some recommended that the HHS levels be modified, generally to be more stringent. A number of commenters suggested standards matching those used by the military. Other commenters, particularly those representing licensees with ongoing drug testing programs, recommended that licensees be allowed discretion to establish cut-off levels more stringent than the minimum specified in the rule. As a compromise, some commenters suggested that laboratory procedures and testing be modified to require them to compile results at both the minimum uniform standard cut-off and the discretionary levels established by the licensees.

These commenters provided different reasons for establishing various cut-off levels, ranging from very stringent to more lenient. A few commenters supported the establishment of cut-off levels based on an objective of establishing a drug-free workplace, recommending essentially zero tolerance and setting cut-off levels just high enough to avoid positives from dietary consumption of legal substances. Others proposed the establishment of cut-off levels that were the lowest (most stringent) levels associated with impairment. Others, sometimes explicitly recognizing that the establishment of cut-off levels involves administrative considerations, recommended the use of "standard" and moderate levels that assist in the establishment of an accepted, widely-used standard and reduce vulnerability to legal challenges. Still others, generally those representing the workers and unions, supported cut-off levels that test for impairment rather than use and that set levels where job performance is probably affected.

A number of licensees commented that they are currently operating drug testing programs which have more stringent (lower) cut-off levels than the HHS Guidelines, especially for marijuana. Commenters were divided in their position regarding adoption of the HHS Guidelines for cut-off levels. Some supported the HHS Guidelines; others supported the more stringent levels proposed by NUMARC. A large number of commenters thought that the HHS cut-off level for marijuana was too lenient, citing experience from ongoing programs that a very high proportion (over 80 percent in Commonwealth Edison's 6-year-old program) of positive marijuana test results fall between 20 and 100 ng/ml. A number of commenters provided specific recommendations for screening and confirmatory cut-off levels for individual drug types.

13.1.5 *Regulation of On-Site Screening Test.* Although the majority of comments in this category addressed specific aspects of on-site testing, several commenters objected to conducting on-site screening tests by licensees on the grounds that such testing should not be conducted by employers and that it would be more costly, create too high a risk of false results, and result in claims of inequitable treatment. Other commenters, principally representatives of licensees and a health care products manufacturer, supported on-site screening tests as effective, timely, and less costly, particularly if only specimens that tested positive in the on-site aliquot test are sent to the certified laboratory. Some commenters favored modification of the proposed rule (§ 26.24[d]) to allow licensees to establish HHS-certified on-site laboratories and to avoid conflict with the HHS Guidelines. Changes in the specified procedures for on-site testing were also recommended, including enabling certified laboratories to match the cut-off levels established by the on-site program. The need for careful attention to conflicts with specific wording in the HHS Guidelines was noted. (Further discussion of the cut-off level issue is provided elsewhere.)

13.1.6 *Requirements for Review of Test Results by a Medical Review Officer.* A number of comments were received concerning the qualifications and role of the Medical Review Officer as specified in the HHS Guidelines, paragraph 2.7(b) (53 FR 11985, dated April 11, 1988). Commenters recommended that, should the HHS Guidelines be generally adopted, these specifications should be modified to eliminate the requirement that the MRO be a licensed physician. They recommended broadening the definition to include other licensed medical care providers with training and knowledge in substance abuse disorders and their treatment, identification and use of controlled substances, and prescription practices of pharmacies, and to provide for consultation of the MRO with a licensed physician for resolution of unusual circumstances. One commenter recommended changing the term "Medical Review Officer" to "Medical Review Professionals" to avoid possible confusion with licensee executive officers.

13.1.7 *Laboratory Certification Procedures.* A number of commenters thought that the number of blind samples was excessive and recommended that the requirement for licensees to submit blind samples be eliminated or substantially reduced. One commenter pointed out the potentially negative effects of having licensees prepare the false documentation associated with blind samples, and others questioned whether a sufficient supply of blind samples would be available on a timely basis. A number of commenters also questioned whether sufficient certified laboratory capacity would be available to implement the proposed rule. Comments both supported and opposed the requirement that laboratories be certified by HHS. Those supporting such certification recommended modification of the proposed rule to specify that licensees are to use HHS-certified laboratories that are directed to conduct drug tests consistent with NRC and licensee requirements. Several other commenters objected to the requirement for HHS certification, noting that it would likely prevent them from using high-quality local laboratories, and would prevent them from testing additional drugs or setting more stringent cut-off levels (unless such modifications are made in the application of the certification process, as discussed above). They recommended that the NRC adopt a provision authorizing licensees to utilize a drug testing laboratory that is either certified via the HHS Guidelines or is certified under a state program that is generally comparable to the HHS program. Other commenters suggested authorization of laboratories certified by The College of American Pathologists Forensic Urine Drug Testing (CAP FUDT) program.

13.1.8 *Splitting Specimen Samples.* A number of commenters recommended the use of split samples to provide an additional quality control measure and to further protect the rights of the workers by allowing a second check on confirmed positive results. Commenters differed in their specific recommendations concerning the number (2 or 3) and specific procedures for testing the reserved sample(s).

13.2 Summary of Responses

13.2.1 *Proposed Alternatives to the HHS Guidelines.* The NRC believes that the rigor required by the HHS Guidelines is not matched by any of the proposed alternatives. The NRC Guidelines address many of the concerns expressed by the commenters. The NRC believes that the highest standards are needed to assure that the testing process is accurate, produces valid results, and provides suitable protection for those being tested.

13.2.2 *Applicability of HHS Guidelines to the Nuclear Power Industry.* The NRC believes that many of the basic requirements of the HHS Guidelines must remain a vital component of the NRC drug testing regulations. However, the NRC is aware that the Guidelines, as written by HHS to apply to testing by Federal agencies, do not perfectly fit the circumstances of the licensees regulated by the NRC. There are many references to legal authorities and other matters that are peculiar to Federal agencies (e.g., references to the Privacy Act, to Executive Order 12564, to the Secretary) and terminology that may be confusing in the NRC-regulated industry context. In addition, the HHS drafted the Guidelines to apply to the physical and organizational circumstances of Federal agencies. Obviously, the circumstances of industries regulated by the NRC are very different from those of Federal agencies. Furthermore, as discussed below, other aspects of the rule, i.e., permission to expand the panel of drugs and establish more stringent cut-off levels, require modification of the HHS Guidelines to facilitate implementation. Consequently, the NRC agrees with many commenters and is, in its rule, directly implementing in its own regulations specific testing program guidelines (an adaption of the HHS Guidelines) that are applicable to NRC licensee fitness-for-duty programs. These testing guidelines are intended to leave intact the safeguards for accuracy and privacy in drug testing established by the HHS Guidelines while ensuring that the parties regulated by the NRC can practically implement the requirements. Editorial changes have been made to the HHS Guidelines to adapt the terminology to the NRC and its licensees' fitness-for-duty programs.

Special note should be made that the list of substances to be tested and cut-off levels established in the testing guidelines are subject to change by the NRC in response to industry experience and changes by the Department of Health and Human Services as advances in technology, additional experience, or other considerations warrant inclusion of additional substances and other concentration levels.

13.2.3 *Limitations in the Panel of Substances That Certified Laboratories Can Test.* Under the HHS Guidelines (2.1[a]), a Federal agency's random drug testing program may test a urine sample *only* for certain specified drugs. The NRC Guidelines at Section 2.1 modify this requirement by expanding the minimum panel of substances for which specimens from the pre-access, for-cause, random, and follow-up testing program are to be tested by adding alcohol in addition to marijuana, cocaine, opiate metabolites, phencyclidine, and amphetamines. Furthermore, the rule will allow licensees to include additional drugs, especially those found to be prevalent in their geographic area. Licensees would be required to develop appropriate test protocols and cut-off levels. For-cause tests are not limited to a specified panel of substances.

In determining which drugs to include in the NRC Guidelines, the Commission assessed evidence regarding the extent of use of the various drugs recommended by commenters and the potential for impairment from the licit use, where appropriate, or abuse of those drugs. The NRC concluded that the panel of drugs in the HHS Guidelines adequately covers the most extensively abused illegal drugs, but does not sufficiently address the major drug class of sedatives (i.e., benzodiazepines and barbiturates). The use and abuse of sedatives by nuclear power plant workers are of significant concern for several reasons.

Although most sedative drugs are obtained legally through prescriptions or in over-the-counter medications, these drugs are subject to abuse. In fact, some researchers have suggested that sedative abuse is more prevalent than the abuse of opiates in this country. In addition, continued abuse of these substances can lead to dependency and "physician-hopping" or illegal behaviors to obtain supplies of the drugs. Consequently, detection of the use of sedatives and an evaluation by the Medical Review Officer of the manner in which a worker is using sedatives are important to prevent the development of sedative-abuse problems.

Of greater significance is that the use of sedatives while on the job, even at physician-prescribed doses, may result in significant impairment. Although many types of performance are detrimentally affected by the use of sedatives, attention and the ability to maintain vigilance are particularly impaired. And, when combined with alcohol, the impairing effects of sedatives, especially bartiturates, are long-lasting and severe. However, to maintain consistency with the HHS program the Commission has decided not to include benzodiazepines and barbiturates in the required panel of drugs at this time. The NRC will further explore this matter with the Secretary of the Department of Health and Human Services, and may issue an amendment to Part 26 if deemed appropriate.

In response to objections by licensees to the requirement that they must consult with local law enforcement authorities and drug counseling services to determine whether other drugs are being used in the geographical locale of the facility and the local workforce and, where appropriate, add these drugs to the list of drugs being tested, the NRC has made this element of the program optional. To address the issue of changing drug use patterns, the NRC may conduct periodic reviews of the minimum drug panel that could result in the inclusion of additional substances.

13.2.4 *Cut-off Levels Defined for Screening and Confirmatory Tests.* In response to comments concerning the appropriate cut-off levels at which samples will be considered positive, the NRC proposes the screening and confirmatory cut-off levels set forth in the NRC "Guidelines for Nuclear Power Plant Drug and Alcohol Testing Programs." These levels define the standards for establishing presumptive positive and negative results for the minimum panel according to the NRC rule. However, in response to numerous comments by licensees, many of whom have existing drug programs with more stringent cut-off levels for the substances included in the proposed minimum drug panel, the NRC rule establishes minimum standards for the panel of drugs and allows licensees the discretion of setting more stringent cut-off levels for these drugs. For example, instead of using their normal cut-off levels for for-cause and follow-up testing, licensees could obtain data on any trace amounts of drugs for medical evaluation of at-risk persons. Certified laboratories are authorized to test and report results at these more stringent cut-off levels, if so requested by the licensee. In keeping with the objective of uniformity and the establishment of a comparable database, however, the laboratories are *also* required to report results for the "standard" cut-off levels established in the rule.

13.2.5 *Regulation of On-Site Screening Test.* Although the NRC is sensitive to the concerns of workers expressed in the comments, the stringent quality assurance requirements of the rule and the rigor of the HHS certification process have convinced the NRC to retain the option of on-site testing. Under the NRC rule, licensees may perform the breath tests for alcohol and the preliminary screening tests of urine specimens provided that the licensee's staff possess the necessary training and skills for the tasks

assigned, their qualifications are documented, and adequate quality controls are implemented. These requirements have been included in the NRC Guidelines. Following preliminary screening, these licensees would submit all presumptive positive specimens and a sample of negative specimens to an HHS-certified laboratory for a second screen and for confirmatory testing. This will substantially reduce the number of specimens that must be packaged, sent, and handled at the certified laboratory. The NRC rule does not prohibit licensees from establishing laboratories and seeking HHS certification. Should HHS certification be obtained, the licensee would be allowed to conduct both screening and confirmatory tests at this laboratory.

13.2.6 *Requirements for Review of Test Results by a Medical Review Officer.* After careful review of the comments received regarding the Medical Review Officer and examination of the *Medical Review Officer Manual* prepared by the Department of Health and Human Services (September 1988), which describes the role and responsibilities of the MRO, the NRC has concluded that this position does require the qualifications of a licensed physician. To maintain consistency with the HHS program, the NRC has decided to retain the title Medical Review Officer.

13.2.7 *Laboratory Certification Procedures.* The NRC has given careful consideration to the number of blind samples licensees must submit to the certified laboratory and has determined that the number specified in the NRC Guidelines is necessary to maintain adequate quality control. In addition, licensees which expand their drug panel beyond the NRC specified minimum panel are responsible for submitting a sufficient number of appropriately "spiked" blind samples to meet equivalent laboratory quality control requirements for those additional drugs. The NRC has consulted with personnel of the Office of Workplace Initiatives in the National Institute on Drug Abuse and has been assured that sufficient blind samples and laboratory capacity will be available to implement the proposed rule on a timely basis.

Given the importance of protecting workers from false positive test results and the absence of clear evidence that alternative certification procedures provide an equivalent level of rigor, the NRC rule maintains the requirement for laboratories to obtain HHS certification in order to perform confirmatory chemical tests on specimens submitted for tests under the provision of the NRC rule. In addition to HHS certification, laboratories used by licensees must demonstrate comparable performance and rigor in testing for the additional substances included in the licensee's specified panel of substances (i.e., the NRC minimum panel plus any discretional additions of the licensee).

13.2.8 *Splitting Specimen Samples.* The NRC is sensitive to the concerns of nuclear power plant workers regarding the adverse consequences of false positive test results and the advantages of using split samples to provide an additional quality control measure and further protect the rights of workers by allowing a second check on confirmed positive results. The first aliquot, along with appropriate chain-of-custody documentation could be (1) transmitted to the HHS-certified laboratory for screening and confirmatory testing or (2) transmitted to the authorized on-site screening laboratory for preliminary testing. The second aliquot of the split sample, along with appropriate chain-of-custody documentation, could be placed in a secure refrigeration unit or forwarded to a second laboratory for retention. Should the specimen test positive, the second aliquot could be tested by the second HHS-certified laboratory.

In the case of on-site screening, the second aliquot could be discarded if the preliminary test (screen) is negative. If the screening test is conducted off-site, the second aliquot could be discarded immediately upon notification of a negative test result for the specimen. Even though there is a high degree of assurance of the accuracy of the test results provided by the chain-of-custody and HHS-certified laboratory procedures, chain-of-custody concerns by tested workers would remain no matter how precise the process or valid the results. Therefore, the NRC has decided not to mandate nor prohibit split samples; the approach may be used by licensees where additional confidence in the process by the workforce is sought.

14.0 Relationship to Access Authorization

14.1 Summary of Comments

This section covers comments relating to the potential overlap of the proposed FFD rule and Industry Guidelines appended to the proposed Access Authorization Policy Statement (AAPS) appearing at 53 FR 7534, March 9, 1988.

14.1.1 *What is an Appropriate "Suitable Inquiry"?.* A number of commenters raised the issue that the "suitable inquiry" requirement in § 26.27(a) is too severe and also conflicts with the background investigation elements section of the AAPS. Proposed § 26.27(a) requires that licensees conduct a suitable inquiry prior to granting unescorted access to determine if a worker has tested positive for drugs in the past. The term "suitable inquiry" as defined in § 26.3 requires verification of employment history for the previous five years and to determine whether the worker had any positive drug tests. Many commenters pointed out that this requirement will be very difficult and costly to meet in part because prior employers will be reluctant, because of liability concerns, to release records of drug use, even with a signed release form. One commenter pointed out, for example, that under § 26.29(b) a licensee would not be authorized to release such information to another employer who is not also a licensee.

The commenters noted that the required background investigation in Section 6.2.1 of the Industry Guidelines appended to the AAPS covers similar material to the fitness-for-duty rule, but is not as severe. The investigation contains several elements, one of which is a check on an applicant's character and reputation including prior illegal use or possession of a controlled substance. Information is to be obtained from four references, two supplied by the applicant and two developed by the utility. Employment verification is to be obtained for a minimum of three years. In addition, the evaluation criteria in Section 7.1 of the AAPS require utilities to assess the impact of past illegal use or possession of a controlled substance.

One commenter pointed out that the proposed suitability inquiry requirements will conflict with the required background checks for security personnel in 10 CFR Part 73, Appendix B. These background checks require the licensee to investigate a number of elements related to selection of security personnel including whether an individual has any history of alcoholism or drug addiction. There are no specific time periods associated with the required background checks.

14.1.2 *Overlap in Training Requirements.* One commenter stated that the training requirements for supervisors and escorts in § 26.22 already exist in Section 9(c) of the Industry Guidelines and that the requirements in the fitness-for-duty rule could therefore be eliminated.

14.1.3 *Relationship of Employee Assistance Programs to the Proposed Access Authorization Policy Statement.* One commenter raised the question of whether a voluntary referral to an

employee assistance program raises an access authorization issue under the Industry Guidelines appended to the proposed access authorization policy statement. Under the Guidelines, illegal use of drugs is an evaluation criterion for unescorted access (§ 7.1[b]) and an element of the continual behavioral observation program (§ 9[a]).

14.1.4 *Temporary Unescorted Access Authorization.* One commenter noted the temporary unescorted access authorization in § 6.4 of the Guidelines and stated that it should be made clear that during the suitable inquiry period, the temporary access authorization would be available.

14.2 Summary of Responses

14.2.1 *What is an Appropriate "Suitable Inquiry"?.* The NRC recognizes the potential overlap between the required background investigations in the fitness-for-duty rule and the proposed AAPS. The NRC agrees that the background investigation required in the fitness-for-duty rule may be difficult to conduct in some cases and that the desired information may not always be forthcoming. Consequently, the term "suitable inquiry" in § 26.3 has been modified to provide for a "best effort" verification, that is, attempts should be made to obtain information for the entire five year period, but under no circumstances may unescorted access be granted based on an employment check of less than three years. In addition, a requirement has been added to § 26.27(a) that a suitable inquiry will be conducted only after obtaining a signed release from the worker or prospective worker authorizing the inquiry.

The NRC recognizes the potential additional requirements under the fitness-for-duty rule as compared to currently required background checks for security personnel contained in Appendix B to Part 73. Nevertheless, the required checks with prior employers in the fitness-for-duty rule are considered necessary for the safety and security reasons noted earlier.

14.2.2 *Overlap in Training Requirements.* The NRC recognizes that there is some overlap in the two training requirements, but does not find any inconsistencies. Moreover, the fitness-for-duty requirements are more comprehensive, to include techniques for recognizing drugs and understanding the role and responsibilities of other fitness-for-duty program elements such as the employee assistance program. Consequently, no changes were made in the final rule.

14.2.3 *Relationship of Employee Assistance Program to the Proposed Access Authorization Policy Statement.* The NRC recognizes that there is a connection between the employee assistance program and proposed access authorization policy statement requirements. Under Section 26.25, employee assistance program staff will provide confidential assistance except where safety considerations must prevail and when the employee assistance program counselor believes that a worker's condition poses a hazard to himself or herself or others. Otherwise, voluntary self-referrals to the employee assistance program are treated confidentially and are not reported to management; therefore, that information would not be available for disclosure in response to an inquiry of previous employers. The NRC is satisfied that there is not an inconsistency in the employee assistance program and proposed access authorization policy statement requirements and consequently no changes are made in the final rule.

14.2.4 *Temporary Unescorted Access Authorization.* NRC agrees that licensees may grant temporary unescorted access authorization provided that all requirements pertaining to the granting of temporary access have been completed and the prospective worker has passed a chemical test. Clarifying language has been added to § 26.27(a).

15.0 Reporting and Recordkeeping

15.1 Summary of Comments

15.1.1 *Fitness-for-Duty Program Performance Data Form.* Many comments on the data form were received. All were severely negative. The consensus was that the stated data requirements are excessive, unnecessary, and expensive and will contribute nothing to the public health and safety. Virtually all respondents asked for deletion of the form and its associated requirements.

15.1.2 *Reports to NRC.* Section 26.73 directs the licensee to provide information concerning fitness-for-duty events. This was presumed to include identities of violators and a record of the incident and its disposition. Some commenters thought that the NRC is not qualified to ensure the necessary degree of confidentiality demanded for these records, while others pointed out that the NRC handles much sensitive information including classified information and thus is well qualified to receive specific fitness-for-duty data. Among the latter, one commenter went so far as to suggest that the NRC, rather than the licensees, implement and administer the violations tracking system. Public Citizen expressed general support of the reporting requirements and recommended that they be augmented to include additional information.

15.1.3 *Reporting Time Requirements.* Section 26.73(a)(2) requires detailed reports on all significant fitness-for-duty events and actions to be made to the NRC Operations Center by phone within 24 hours and in writing within 30 days. Many commenters claimed that the 24-hour requirement is excessive. Others pointed out conflicts or potential conflicts between reporting requirements in the fitness-for-duty rule and those cited in 10 CFR 73.71, 10 CFR 50.72, and Reg. Guide 5.62.

15.1.4 *Incident Locale.* Commenters posed questions as to whether drug or alcohol-related incidents should be reported if they occur outside protected areas—either on-site or off-site.

15.2 Summary of Responses

15.2.1 *Fitness-for-Duty Program Performance Data Form.* The NRC does not believe that collection of data in a standard format unnecessarily burdens licensees. Collecting data in a standard format would assure that appropriate data is collected, and would facilitate periodic analysis and audits. Certain information is necessary for the NRC to evaluate the effectiveness of the rule (and if necessary, make appropriate improvements or changes) and industry programs and a standard data format would provide a tool for the Commission's periodic review program. No specific improvements to the form were suggested by commenters. However, NUMARC has developed and proposed to the NRC a standard form for data collection. The NRC will specify only the general types of data to be collected in the rule with the expectation that all power reactor licensees will use an NRC-approved NUMARC form.

15.2.2 *Reports to NRC.* The NRC sees no reason to change the rule in response to comments that sensitive information not be provided. The reporting requirements in § 26.73 have been modified to add alcohol and delete written reports of reportable events. The rule has been modified to require periodic submittal of program performance data.

15.2.3 *Reporting Time Requirements.* The NRC will maintain the 24-hour reporting deadline for fitness-for-duty events involving licensed operators and supervisory personnel. Licensees should note that this provision supersedes and relaxes the 1-hour reporting period required for the fitness-for-duty

categories of safeguards events in 10 CFR 73.71. The NRC will publish a revision to Regulatory Guide 5.62 to ensure consistency with this rule.

15.2.4 *Incident Locale.* The NRC has modified the wording of § 26.73, "Reporting Requirements," to make it clear that incidents involving licensed operators or supervisory personnel occurring off-site or external to protected areas must be reported.

16.0 Audits of Fitness-for-Duty Programs

16.1 Summary of Comments

Approximately one-third of the comments received concerning audits of fitness-for-duty programs addressed the frequency requirement for the audits, which is 13 months in the proposed rule. The majority of these commenters stated that the rule should be revised to require an audit every three years, after an initial audit is performed within 13 months of implementation of the program. Most of the other commenters stated that the audit frequency should be once every three or five years. One commenter stated that the audit period should remain on a 13-month cycle.

Two commenters questioned how information that is protected under § 26.29(b) can be used when sharing audit results of contractors as described in § 26.80(a). Section 26.29(b) prohibits disclosing some of the information that would be collected during an audit.

Many commenters stated that the word "effectiveness" in §§ 26.80(a) and 26.80(b) is too subjective and that "compliance with the regulations" should be the requirement.

Several commenters stated that the phrase in § 26.80(b), "individuals qualified in the subjects being audited," should be clarified.

One commenter stated that § 26.80(a) should be revised to delete the requirement for the licensee to be responsible for the effectiveness of contractor programs and implementation of appropriate corrective action for contractor programs since this should be the contractor's responsibility.

Two commenters stated that § 26.80(a) should be clarified as to whether or not a licensee may accept audits for contractors conducted by other licensees.

One commenter stated that the requirement in §§ 26.80(a) and 26.80(c) that audit reports be maintained on-site and at corporate headquarters be changed to corporate headquarters only. The basis for this comment is that some utilities have several reactor sites and maintaining the reports at each site would be a redundant effort.

16.2 Summary of Responses

The NRC has maintained the § 26.80(a) requirement for an audit frequency of nominally every 12 months. This decision is based on the need to assure the reliability and accuracy of chemical testing procedures. As industry experience with fitness-for-duty programs accumulates and is made available to the NRC, the Commission may re-evaluate the frequency of required audits, as warranted.

The NRC agrees that §§ 26.29(b) and 26.80(a) of the proposed rule contained a conflict concerning protection of information. Section 26.29(b) has been revised to explicitly allow licensees to have access to personal information that may need to be examined during audits.

The NRC intentionally has used the word "effectiveness" throughout the rule to ensure that all affected parties maintain an overall concern for the rule's objectives rather than focusing on documentation of program compliance with "the letter of the law." Although compliance is important, the Commission's over-riding concern is an answer to the question, "Is the program working?"

The NRC believes that current wording in the rule is adequate to define auditor qualifications. The intent of this section is to ensure that an individual, for example, who is not a licensed physician and has no knowledge of substance abuse is not assigned to evaluate the effectiveness of a particular Medical Review Officer's decision making. Similarly, the NRC expects that persons who are evaluating testing laboratories will be knowledgeable about the forensic implications of laboratory procedures. Because individuals who possess the requisite skills to conduct these audits are likely to be relatively rare and their services needed only infrequently, licensees will probably find it necessary to contract for appropriate audit staff rather than staffing an entire audit team from the licensee's Quality Assurance Program. Current wording in the rule is intended to recognize and encourage such an approach to staffing program audits.

The NRC does not agree with the commenter who suggested that licensees should not be responsible for contractor programs. As noted in the discussion of comments pertaining to the scope of the rule, the licensee is the granting authority for unescorted access to protected areas and so is responsible for the fitness-for-duty and the reliability of any individuals to whom unescorted access is granted, whether contractor or licensee employee. Only by monitoring the effectiveness of contractor programs that the licensee accepts and requiring necessary changes can the licensee be assured that the trust implied by the granting of unescorted access is warranted.

The intent of the wording in the proposed rule is to reduce the burden on licensees by allowing audits of contractors to be shared between licensees and to reduce the burden on contractors who provide personnel to several utilities by reducing the number of required audits. However, each licensee has the ultimate responsibility to ensure that all contractors performing activities within the scope of the rule comply with the rule.

The NRC agrees it is unnecessary to dictate where the licensees should maintain copies of the audit reports as long as a copy is available for NRC inspection. Section 26.80(a) has been changed accordingly.

17.0 Implementation Schedule

17.1 Summary of Comments

The NRC received numerous comments on the proposed implementation schedule for the rule. Eighteen comments were received from individual licensees. In addition, a number of other licensees submitted letters endorsing the NUMARC position on the rule as a whole, including NUMARC's position on the implementation schedule. Commenters generally agreed that 90 days was insufficient time to implement the provisions of the rule. Problems with the development of training material, modification of existing EAPs, development of administrative procedures, negotiations with unions, and the establishment of contracts with chemical testing laboratories were cited by many of the commenters as reasons for the need for a longer period for implementation. Most commenters suggested that 180 days be allowed for implementation of all provisions of the rule. Some commenters proposed that additional time beyond 180 days be allowed for the implementation of the random testing provisions of the rule.

17.2 Summary of Responses

The NRC places a high priority on the implementation of the fitness-for-duty programs and policies required by the present rule. Many licensees already have in place most of the key program elements. However, because of the complex provisions of the rule, the need for some licensees to establish contractual relations with laboratories,

the need to develop implementation procedures, the need to augment existing training materials, and the need to coordinate the provisions of the rule with numerous contractors and negotiate with unions, the NRC is convinced that the quality of the programs will be enhanced by extending the implementation of all provisions of the rule until 180 days after the effective date of the final rule. Because of the importance of the rule, the NRC cannot support the further extension of the implementation of the random testing provision of the rule past the 180-day deadline.

Although licensees need not submit written policies and procedures to the NRC for approval prior to implementing their programs, the Commission has reserved to itself the authority to review the program at any time to assure that the program meets the performance objectives of the rule. If the review or other inspections detect a shortcoming in the program, the Commission can then require corrective action.

18.0 Legal Issues

18.1 Summary of Comments

18.1.1 *Constitutionality of Rule.* Several commenters noted that significant issues of constitutionality with regard to drug testing in the workplace have been raised under the Fourth Amendment and that these issues are currently being reviewed within the judicial system. Two drug testing cases are on the current calendar of the United States Supreme Court. (*National Treasury Employees Union* v. *Von Raab*, 816 F.2d 170 (5th Cir. 1987), *cert. granted*, 108 S.Ct. 1072 (1988); *Railway Labor Executives Association* v. *Burnley*, 839 F.2d 575 (9th Cir. 1988), *cert. granted*, 108 S.Ct. 2033 (1988)). Generally, commenters representing operators of power reactors support the constitutionality of the rule, while commenters representing labor organizations or individuals challenge the rule's constitutionality. A few of these commenters suggested that the Commission delay its rule until the Supreme Court has acted on the cases before it.

A few commenters stated that the taking of the urine sample for analysis presented a violation of a person's right of privacy under the First Amendment to the Constitution.

A few commenters questioned whether the rule might not violate the self incrimination provision of the Fifth Amendment to the Constitution, in particular with regard to the potential for release of adverse test results to local police.

18.1.2 *Federal Rehabilitation Act.* A few commenters suggested that the Commission should address the Federal Rehabilitation Act of 1973, as amended by the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978 (29 U.S.C. 701–796) in relation to its fitness-for-duty rule.

18.1.3 *Preemption of State and Local Laws.* Several commenters noted that some states have enacted laws that appear to conflict with the Commission's rule, and requested clarification whether the Commission's rule would be preemptive of state and local law.

18.1.4 *Appeal Procedure.* Some commenters questioned the need for and scope of the appeal procedure required by the rule. Reference to due process was seen as importing unnecessarily complicated judicial type procedures, and that fairness was the goal. Reference to collective bargaining procedures was viewed as undesirable because those procedures often incorporate binding arbitration which would also unduly complicate the appeal of denial of unescorted access because of an adverse fitness-for-duty finding. Finally, appeals should be limited to permanent employees of the licensee and not be extended to the employees of contractors.

18.1.5 *Protection of Information.* Some commenters raised questions about the protection of information, specifically reporting of information to local police, and disclosure of information to arbitrators and the affected individuals. One commenter asked the Commission to address the relationship between protection of information under the Commission's rule and the information protection requirements of 42 CFR Part 2, dealing with drug and alcohol abuse treatment programs.

18.1.6 *Collective Bargaining Rights.* A commenter raised a question about the relationship of the Commission's rule to the rights of workers under the National Labor Relations Act to bargain over conditions of employment and asked that the Commission state its position.

18.1.7 *Employee Assistance Program.* A commenter asked for the Commission to indicate its legal authority for including employee assistance programs in the rule.

18.1.8 *Administrative Procedures for Alcohol.* A few commenters questioned whether the notice of proposed rulemaking was adequate to address issues regarding alcohol use and to support the inclusion of alcohol-related provisions in the final rule.

18.2 Summary of Responses

18.2.1 *Constitutionality of Rule.* It is the Commission's considered opinion at this point that continued assurance of nuclear safety in the operation of power reactors fully justifies the rule being promulgated. The imperatives of safe operation of nuclear power reactors demand a workplace where the reliability, integrity and physical and mental fitness for their assigned duties of all categories of workers with unescorted access to plant equipment is unquestioned. The program being mandated by this rule is reasonably related to the achievement of the Commission's safety objective. The Commission has no doubt that the rule will significantly enhance safety of operations at nuclear power reactors. It goes without saying, however, that the Commission will review this rule in light of relevant future Supreme Court decisions, and make whatever revisions those decisions require.

The two cases cited above were decided on March 21, 1989 in favor of drug testing as presented by the circumstances of those cases (*Skinner* v. *Railway Labor Executives Association.* No. 87–1555; and *National Treasury Employees Union* v. *Von Raab.* No. 86–1879). Neither presented issues to the Court for its consideration in the context of the imperatives of nuclear safety nor addressed random testing. However, the logic of those cases gives the Commission added assurance that this rule represents a proper and prudent regulatory action for the protection of public health and safety.

It is already well established that persons working in nuclear power plants have diminished expectations of privacy in the workplace with respect to fitness-for-duty issues. For example, control room operators are licensed under rules (10 CFR Part 55) that require medical examination biennially and general good health. Security personnel are subject to medical and mental qualifications, including use of alcohol and drugs (see 10 CFR Part 73, Appendix B). All personnel and their hand-carried items (such as lunch boxes) are subject to search upon entering the protected areas of nuclear power plants, including pat down searches when metal and explosive detectors are not working or when there is suspicion that the person may be attempting to bring proscribed items into the protected area (see 10 CFR 73.55). Most, if not all, licensees of nuclear power plants also are committed through their security plans under 10 CFR Part 73, to conduct background investigations, administer psychological

examinations, and observe employees for indications of aberrant behavior. Licensees also have behavioral observation programs that follow Edison Electric Institute guidelines. Finally, all persons with unescorted access to nuclear power plants are, by Federal law, subject to a criminal history records check that requires the taking of fingerprints and the submission of the fingerprints to the Federal Bureau of Investigation (see 10 CFR 73.57). The provision of a urine sample or taking of a breathalyzer test is a small increment in the diminished expectation of privacy under which persons work in a nuclear power plant. Accordingly, the Commission concludes that its rule does not constitute an unconstitutional invasion of the right of privacy. Indeed, persons working in nuclear power plants may already be considered to be highly regulated, and, in regard to Fourth Amendment issues, within the ambit of *Shoemaker* v. *Handel*, 795 F.2d 1136 (3rd Cir. 1986), *cert. denied*, 479 U.S. 986 (1986).

On the assumption that the rule being promulgated is within the Constitution in other respects, the rule's provisions on protection of information do not infringe upon the right of a person to not incriminate himself. In the Commission's view, the case of *Schmerber* v. *California*, 384 U.S. 757 (1966) controls the issue. In that case, the Court upheld the taking of a blood sample for alcohol analysis against a Fifth Amendment challenge. A urine sample is no more incriminating.

18.2.2 *Federal Rehabilitation Act.* The Federal Rehabilitation Act of 1973, as amended, does not include, within the concept of "handicapped person", an individual who is an alcohol or drug abuser whose current use of alcohol or drugs prevents that individual from performing the duties of the job in question or whose employment, by reason of such current alcohol or drug abuse, would constitute a direct threat to property or the safety of others (see 10 CFR 4.101(a) and 29 U.S.C. 706(7)(B)).

An individual whose urine or breath sample tests positive for drugs or alcohol is obviously a current user whose continued unescorted access to plant equipment constitutes a threat to nuclear safety. However, a person who enters into an employee assistance program and whose subsequent tests are negative is not a current user and would be entitled to the protection of the Federal Rehabilitation Act if it were applicable to his place of work because of his employer's receipt of or benefit from Federal financial assistance. Federal financial assistance is defined at 10 CFR 4.4(d) and means essentially the provision by the Federal Government of any funds or personnel or property free of charge or at reduced rates. The Commission does not provide any Federal financial assistance to nuclear power reactor licensees. On the contrary, the Commission charges power reactor licensees for the regulatory services it renders (see 10 CFR Parts 170 and 171). Whether or not other Federal agencies provide such assistance is not known to the Commission. Each licensee implementing the Commission's fitness-for-duty rule will need to determine for itself whether it is receiving such assistance.

18.2.3 *Preemption of State and Local Laws.* The Atomic Energy Act of 1954, as amended, preempts to the Federal Government the field of regulation of nuclear power reactors in all matters pertaining to radiological safety of operation. See 10 CFR 8.4, *Pacific Gas and Electric Co.*, v. *State Energy Resources Conservation and Development Comm.*, 461 U.S. 190 (1983). However, State laws on possession, sale or use of controlled substances and alcohol were enacted with broad social goals in mind rather than radiological safety. Thus, such laws would not be preempted. There would be preemption in the rare case where a State sought to control fitness-for-duty of nuclear plant employees for radiological safety purposes or a State law made compliance with NRC's fitness-for-duty rule difficult or impossible.

18.2.4 *Appeal Procedure.* The Commission believes that an appeal or review procedure with respect to positive alcohol or drug determinations is needed because elementary fairness to the adversely affected individual will help assure employee cooperation in the implementation of the licensee's program. Such cooperation should contribute to successful implementation of the rule. Fairness is represented in the rule by the employee assistance program, the appeal procedure, and the protection of information. Therefore, the appeal procedure is retained, but modified to replace reference to due process with reference to impartiality and objectivity and removal of reference to collective bargaining agreements. Because the focus of the rule is on fitness for unescorted access and not directed at an employment relationship, and because the licensee will be making the access determination based on fitness-for-duty for all persons needing unescorted access, whether they are permanent employees, temporary employees or contractor employees, the procedure is not being limited to permanent employees of the licensee. The Commission notes, however, that in union plants the review procedure covers drug and alcohol issues subject to collective bargaining and that the removal of the reference to collective bargaining agreements in the rule does not preclude bargained for procedures, including binding arbitration, from being employed in resolving disputes over fitness-for-duty determinations. The allowance of an internal management review is discretionary only, and not mandatory except in the absence of any other procedure.

18.2.5 *Protection of Information.* It is not the Commission's intention that results of testing be routinely available to local law enforcement agencies except under court order since the test result does not, in and of itself, demonstrate whether the use of the drug or alcohol was on-site or off-site, legal or illegal. The Commission is, however, firmly convinced that on-site criminal conduct, such as sale or possession of illegal substances, not be protected by the Commission's rule. The Commission agrees that the individual to whom the information pertains should be able to see the records in which the information is contained. The Commission also agrees that such records should be available to an arbitrator, or other adjudicator who is being asked to resolve a fitness-for-duty dispute, provided the records are relevant to the particular dispute. Section 26.29 has been modified to clarify its application accordingly.

With regard to 42 CFR Part 2, it is the Commission's conclusion that it has no relationship to the Commission's rule. 42 CFR Part 2 comprises the regulations of the Department of Health and Human Services implementing Section 408 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (42 U.S.C. 290 et. seq.). It states the rules for maintaining confidentiality of patient records for persons in drug or alcohol abuse prevention and treatment programs regulated by or receiving assistance from the United States Government. First, the Commission is providing no assistance to any such program in the private sector. Second, it is not regulating such a program. The requirement for an employee assistance program does not mandate a treatment program that would fall under the regulations in 42 CFR Part 2. As noted in the response to the issue of preemption, the employee assistance program is not a preempted area. Its content is open to bargaining and the application of other nonconflicting State laws. Further,

licensees are not precluded from referring employees to treatment programs to which the HHS rules might apply as long as the minimum program required by section 26.25 is provided by the licensee. In that case outside patient records would be totally separate from records required by 10 CFR Part 26 and would be protected according to other applicable rules.

18.2.6 *Collective Bargaining Rights.* According to Memorandum GC 87–5, issued by the General Counsel of the National Labor Relations Board on September 8, 1987, drug or alcohol testing for current employees and job applicants is a mandatory subject of collective bargaining and that the implementation of a drug or alcohol testing program is a substantial change in working conditions. Although the Commission's rule requires a drug and alcohol testing program and sets certain standards for it, the rule is not one directed at labor relations, but rather at nuclear safety. The Commission's rule applies equally to union and nonunion workers. It does not affect, even indirectly, the right of self-organization provided by the National Labor Relations Act. The rule does not preclude collective bargaining over issues in drug or alcohol testing programs that are not addressed by it. In the Commission's view, its rule and the opinion of the NLRB General Counsel are compatible documents. See, *Metropolitan Life Insurance Co.* v. *Massachusetts*, 471 U.S. 724, 755 (1985).

18.2.7 *Employee Assistance Program.* The authority statement for the rule states that it is promulgated under Section 161, among others, of the Atomic Energy Act. Included within Section 161 is section 161i(3) which gives the Commission authority to promulgate rules to govern any activity authorized pursuant to the Atomic Energy Act, including operation of facilities, to protect health and safety. The employee assistance program required by the rule is an incremental addition to safety by giving persons with fitness-for-duty problems a nonthreatening avenue to resolve those problems, thus removing a potential for compromising the safety of operation of a nuclear power reactor. In the Commission's view the employee assistance program can be incorporated in a Commission rule under the broad scope of Section 161 of the Atomic Energy Act.

18.2.8 *Administrative Procedures for Alcohol.* Under the Administrative Procedure Act (5 U.S.C. 553) the Commission is obligated to provide in its notice of proposed rulemaking either the terms or substance of the proposed rule or a description of the subject and issues involved. With respect to alcohol, the proposed rule specifically included it in the scope of the licensees' fitness-for-duty programs (§ 26.20). The performance objectives are applicable to any substance, legal or illegal, that can adversely affect a person's ability to perform. There is no doubt that alcohol is such a substance. The rule text did not, however, include prescriptive requirements for alcohol. However, the Commission expressly asked for comment on the extent to which guidance should be given as to alcohol and prescription drugs. Standards for blood alcohol content were extensively discussed in the Statement of Considerations along with a Commission request for comment on whether the Commission should prescribe a cutoff level for alcohol. Thus, the notice of proposed rulemaking clearly covered alcohol both in the terms of the proposed rule and in describing in some detail the subject and issues involved. The public was well advised that alcohol testing was a subject within the rulemaking and that the Commission expected to resolve basic issues regarding testing for alcohol in the comment period on the proposed rule. Therefore, the inclusion in the final rule of basic additional requirements for alcohol testing is, in the Commission's view, well within the scope of the proposal. There is no requirement that the additional rule text dealing with alcohol testing be published for separate comment, and not as part of the final rule.

19.0 Costs/Benefits

19.1 Summary of Comments

Several commenters stated that the NRC should justify the rulemaking under the provisions of § 50.109(a)(3), however, no commenters supported the alternative that a backfitting analysis is not necessary under the provisions of § 50.109(a)(ii).

Several commenters said that the estimated costs in the Backfit Analysis were substantially underestimated in the following cost element areas: costs to administer the testing and training programs, particularly the estimate of the numbers of additional staff that would be necessary to administer the program; length of time estimated for individual employee training, both initial and refresher; time to take a test between leaving and returning to work area; added cost of using HHS certified laboratories and quality control measures; and, costs to conduct background checks.

In addition to these comments, one person, whose comments were included as enclosures by two respondents from one union, contended that: the number of persons that would be tested is underestimated and did not include contractor personnel; incremental costs are incorrect because not all plants have fully developed programs; average life of plants should be 40 years rather than 25; use of 10 percent discount rate is unrealistic; and, costs associated with alcohol, legal drug use, and other kinds of performance impairment were ignored.

This commenter also contends that: written policies and procedures and labor contract modifications involve recurring as well as initial costs; employee turnover needs to be factored into training and testing; costs of employee assistance programs do not include medical and counseling staff, training materials, and medical testing and treatment; costs of legal challenges resulting from the program omitted awards of back pay and/or damages and underestimated volume of appeals; and, indirect costs to workers from false positives (lost jobs or wages, humiliation, etc.) are not included.

In addition to these cost comments, one person, whose comments were included as enclosures by two respondents from one union, contended that benefits are overestimated and not documented. In particular, the commenter challenged: benefits of reduction in lost productivity due to employees being unfit for duty; the nexus between use of illegal drugs and impairment of work performance; and, reduction in insurance rates resulting from more comprehensive drug testing.

19.2 Summary of Responses

The NRC agrees with the comments that the rulemaking should be justified under the provisions of 10 CFR 50.109 (a)(3). The Backfit Analysis has been modified based on consideration of the above cost comments as follows:

19.2.1 *Cost to Administer the Testing and Training Programs.* Staff agrees and has adjusted the cost estimate to include the costs of:

a. Additional personnel to administer the testing and training programs;

b. One person for program administration and recordkeeping;

c. One person for collection and processing of specimens; and

d. A Medical Review Officer.

Miscellaneous costs have also been increased to better reflect the costs of forms and record development, and the costs of protected storage for records.

19.2.2 *Length of Time for Individual Training.* Based on the comments, the estimate of training costs has been adjusted to reflect the following:

(a) At least one hour of initial training for *all* employees;

(b) At least four *additional* hours of initial training for supervisors.

19.2.3 *Time to Take a Test.* Several commenters noted that the estimate of 30 minutes of an employee's lost productive time is too low. Lost productive time can include time to secure and restart work in progress and travel between the employee's work station and the specimen collection station. The Backfit Analysis estimate was based on an assumption of 15 minutes for travel to and from the collection site and 15 minutes at the collection station. This was based on the assumption that the majority of employees tested would have work stations within the protected area, and that at most sites the collection station would be efficiently located in or near the protected area to accommodate the large number of tests to be conducted. Also, the staff had assumed that after selecting an individual for testing on a given day, selection of when the test will be conducted that day would take into account holding down lost production time. Staff discussed these assumptions with licensees who have been conducting testing. Some suggested 90 minutes might be appropriate. Other licensees questioned said that 30 minutes is adequate, but that longer times could result from administrative inefficiencies. Based on the comments and the further discussions the estimated time has been increased to 60 minutes.

19.2.4 *Added Cost of Using HHS-Certified Laboratories and Quality Control Measures.* Staff reexamined the cost estimates of initial and confirmatory tests by contacting three laboratories to determine their charges for initial screening and confirmatory tests. Prices quoted were $16, $17, $20, and $25 per initial test, and $50, $65, and $75 per confirmatory test. The lab that was on the high end for initial test cost was on the low end for confirmatory test cost, and had two prices, which depended on the number of samples in the contract. It is speculative to assess whether the labs contacted would have to undergo any additional expenditures to be so certified and whether they would pass such costs on to their customers or would absorb those costs to remain competitive. Costs could go down due to economies of scale, but could go up initially due to increased demand for certified labs exceeding the supply. Staff sees no compelling reason to change the Backfit Analysis cost estimates of $20 per initial screening and $75 per confirmatory test.

An additional cost of quality control is the blind samples to be included along with the employee specimens. The Backfit Analysis included a cost to the utilities of $50 per blind performance test specimen. This cost is in addition to the cost of initial screening and confirmatory tests on these specimens. Staff believes that this is a reasonable representation of the quality control costs that will be incurred, and has made no change to this cost.

19.2.5 *Costs to Conduct Background Checks.* The staff disagrees that there is a need to include the costs of conducting background checks in the incremental cost estimate. Industry has already committed to these background checks through NUMARC in its Access Authorization Program, and thus costs associated with background checks would be expended regardless of whether or not they were required by the Fitness-For-Duty Rule.

19.2.6 *Number of Persons to be Tested.* The Backfit Analysis assumed an average of 1500 employees and contractors would be tested randomly at each plant. This estimate was based on experience with the fingerprint cards submitted to the NRC in compliance with 10 CFR 73.57, which requires these cards to be submitted for all persons granted unescorted access to the protected area. This is the same population as would be covered by the Fitness-For-Duty Rule. After receiving the comments, staff checked these estimates with several licensees and was satisfied that the estimate is appropriate. Staff disagrees that any change is needed to this element of the cost estimate.

19.2.7 *Incremental Costs.* The comment that not all plants have fully developed programs would be inconsistent with full implementation of industry commitments to follow the EEI guidelines. Any costs incurred because commitments have not been met are considered costs for corrective action and not an impact of the present rulemaking.

19.2.8 *Average Life of Plants.* The NRC issues licenses with a 40 year limit. For many plants this time starts at the date of the construction permit, resulting in 30 years remaining for operation. Some plants are being licensed for 40 years from the date of the operating license, resulting in a longer operating period. Some plants are just beginning their operations while others have already been operating under license for many years. Whether the useful life of some will be extended through license renewal is somewhat speculative and has not been considered. However, the effect on the total cost will be small in any event because costs beyond 25 years contribute little to the total cost in the present worth approach the NRC is using for its cost estimates.

19.2.9 *Use of 10 Percent Discount Rate.* The NRC uses a 10 percent discount rate in its regulatory impact analyses to be consistent with applicable OMB guidance. Because of concerns that this rate may be unrealistic at the present time, the NRC also shows the costs associated with a perhaps more realistic 5 percent discount rate.

19.2.10 *Costs Associated with Other Performance Impairments.* Staff disagrees that any change to the Backfit Analysis is needed for these costs. Activities associated with preventing alcohol abuse, legal drug use, and other kinds of performance impairment consist of training, testing and employee assistance programs. The costs assumed for these cost elements already cover these activities.

19.2.11 *Recurring Costs.* The staff disagrees that any change to the Backfit Analysis is needed for recurring costs of written procedures and contract modifications. Staff agrees that licensees incur recurring costs for periodic revision to these documents, but sees no significant difference to these recurring costs attributable to the Fitness-For-Duty Rule. Costs of periodic revisions would accrue even without the Fitness-For-Duty Rule. Furthermore, only the costs for compliance with the rule need be considered, not costs of elective changes. The Backfit Analysis contains only the one time cost to modify these documents to meet the rule requirements.

19.2.12 *Employee Turnover.* One commenter noted that the NRC seemed to assume an employee turnover rate of zero. Staff recognizes that newly hired workers also would need orientation training, but considers this to not add to the incremental costs because such training is already part of the industry's existing fitness-for-duty programs. Staff considers the one time cost for current employees to be an additional cost beyond the current industry fitness-for-duty costs because the revisions to the industry program at many plants will require retraining of existing staff in these new procedures and rules of employment insofar as they differ from existing fitness-for-duty procedures and rules of employment. Staff disagrees that any change to the incremental costs is needed for employee turnover.

19.2.13 *Costs of Employee Assistance Programs.* Staff agrees that the costs of medical and counseling staff, training materials, and medical testing and treatment were underestimated, and has revised the Backfit Analysis to include additional personnel to administer the testing and training programs, in addition to the additional employee assistance program staff provided for in the draft analysis.

19.2.14 *Costs of Legal Challenges.* Staff agrees that there may be some costs associated with these legal challenges, but has no basis for assessing these costs. Attention to quality controls, whose costs were included, should serve to minimize these legal costs.

19.2.15 *Indirect Costs to Workers from False Positives.* The program has been designed to essentially eliminate false positives by use of diverse state of the art testing procedures and quality controls, including the use of certified laboratories, blind samples, chains of custody, and retention of portions of specimens for retesting. The staff agrees that the costs to an individual could be substantial should such an event occur but has not included these indirect costs in a quantitative manner for lack of a means for estimating them fairly. The NRC has considered these indirect costs in a qualitative sense, and has determined that the benefits warrant any such indirect costs (which are highly unlikely) in addition to the quantified direct costs.

19.2.16 *Benefits Overestimated.* Benefits are described in Items 3 and 4 of the Backfit Analysis. The latter included the statement that, in addition to the more important benefits of preventing unacceptable risk to the public from radiological releases, benefits will likely accrue to licensees from the potential reduction in absenteeism, lost worker productivity, medical and insurance costs, and plant downtime. Staff agrees that these claimed benefits have not been quantified or documented. Staff did not intend to imply that the cost reductions associated with these benefits would outweigh the costs of implementation of the Fitness-For-Duty Program, only that these benefits would exist and would serve to somewhat offset the expenses of the program. Lack of quantification of these benefits tends to make the Backfit Analysis cost increase estimates conservative.

With respect to the relationship of illegal drugs and impairment of work performance, see discussion under Item 3, Impairment *vs* Reliability, above, and NUREG/CR 5227, "Fitness-For-Duty in the Nuclear Power Industry: A Review of the Technical Issues."

Summary of Significant Changes From the Proposed Rule

The NRC amended several sections of the proposed rule in response to comments received from the public on the issues and in response to questions raised in the Notice of Proposed Rulemaking. The following is a summary of the significant changes.

The scope of the rule was amended to include power reactors under construction and to extend the date for implementation of all requirements to 180 days after the effective date of the rule.

The definition of "confirmed positive test" was amended to clarify that the test is not a confirmed positive until the Medical Review Officer has reviewed the test results. The Medical Review Officer's review must be completed and licensee management notified within 10 days of the initial presumptive positive screening test.

The definition of "suitable inquiry" was amended to clarify that a best-effort verification of employment history is intended. A conforming amendment was made to the management actions section that required the inquiry.

The general performance objectives were amended to clearly show that the reliability and trustworthiness of nuclear power plant personnel must also be assured.

The requirements for written policies and procedures were amended to include a prohibition against the consumption of alcohol prior to and during work, and the requirement to address situations where a person has been called in to perform unscheduled work.

The requirements for training of escorts have been amended to clarify NRC's intent that escorts need not be trained as supervisors.

The period in which a test must be performed prior to the initial granting of unescorted access was specified as 60 days.

The random testing rate was established as 100 percent per year.

The basis for for-cause tests was clarified.

NRC testing guidelines modeled after the HHS Guidelines, have been developed as the standards for the collection, protection, and testing of specimens for drugs and alcohol.

Licensees will be required to certify to the NRC that their fitness-for-duty programs have been implemented.

Testing laboratories shall be laboratories certified by the Department of Health and Human Services.

A requirement has been added to limit access to the results of preliminary tests.

Tests for alcohol are required to be performed in conjunction with other substance tests. Tests are to be administered by a breath analysis. A confirmatory test may be done with another breath measurement instrument, or if demanded by the person being tested, by gas chromatography analysis of blood.

The requirements for management actions were revised to add the use of alcohol which resulted in on-duty impairment as a subject of the inquiry to previous employers.

The requirement for making available information concerning prior violations of a fitness-for-duty program was amended to include a requirement that the inquiry be supported by a signed release from the individual being investigated.

The frequency of unannounced tests following reinstatement was amended to require more frequent testing for the first four months.

A requirement was added to the section on management actions for licensees to impose sufficient sanctions for alcohol. prescription drugs and over-the-counter drugs to deter substance substitution.

The appeals process requirements were clarified.

The requirements to protect information have been amended to clarify that personal information can be disclosed to persons deciding matters on review or appeal, to persons pursuant to a court order, and to auditors (in addition to those listed in the proposed rule).

Records retention periods have been changed to five years.

A requirement was added for licensees to periodically submit program performance data.

Reporting requirements have been amended to include abuse of alcohol onsite by a licensed reactor operator or supervisory personnel.

The requirement to maintain a copy of the audit report onsite has been deleted.

Modification of Enforcement Policy

The Commission is modifying its General Statement of Policy and Procedure for NRC Enforcement Actions, 10 CFR Part 2, Appendix C (Enforcement Policy) to reflect the Commission's new rule on Fitness-For-Duty, 10 CFR Part 26. The changes to the Enforcement Policy are being published concurrently with the new rule.

The modifications to the Enforcement Policy are being made in Supplement VII "Miscellaneous Matters" to provide

examples of violations of fitness-for-duty requirements. The examples are A.6, B.6, B.7, B.8, C.6, C.7, C.8, C.9, D.4, D.5, and E.4. As with the examples in the other Supplements to the Enforcement Policy, the new examples are neither controlling nor exhaustive nor do they establish new requirements. The examples are to be used as guidance in considering the severity levels of violations of requirements.

In developing the examples, the Commission notes that it is not the unfit person that establishes the violation but rather the licensee's failures, including those of its contractors and vendors, that create violation. For example, if the licensee has effectively implemented its fitness-for-duty program meeting NRC requirements and, based on behavior observation, identifies and removes a person not fit for duty, there may not be a regulatory violation.

The example for Severity Level I is of very significant concern because it represents the failure to implement a fitness-for-duty program. This example would be applicable to a situation where essentially the licensee does not have a program in place.

The examples for Severity Level II are also very significant because they involve the failure to take action when there is the potential to have a direct impact on safety-related activities.

The examples for Severity Level III are significant because they represent significant individual violations or significant breakdowns in basic elements of a fitness-for-duty program. Basic elements include important aspects of the program, such as: training, appeals, records, testing integrity, randomness in testing, audits, prescreening, management response, contractor oversight, and employee assistance. A breakdown in the program categorized at a Severity Level III will normally involve more than one signficant failure of a single element or single failures of a number of elements. In addition, a failure to ensure that specimens collected in accordance with 10 CFR Part 26 are not used for purposes other than those provided by the rule without the permission of the tested individual may also be considered a significant violation.

Severity Level IV and V violations are matters which, while requiring correction, are less significant to the overall fitness-for-duty program.

Enforcement in Other Licensed Activities

The Commission notes that this rule applies to 10 CFR Part 50 licensees only, it does not establish standards or criteria to be applied to licensed activities conducted under any other Part of its regulations. This limited application of Part 26 does not mean, however, that the Commission will not respond to fitness-for-duty issues involving other licensees that affect health and safety. Under the Atomic Energy Act of 1954, as amended, and its regulations, the Commission may respond to such cases by the issuance of appropriate orders.

As explained in the Commission's Enforcement Policy (see 53 FR 40027, Thursday, October 13, 1988), the Commission may take enforcement action where the conduct of the individual places in question the NRC's reasonable assurance that licensed activities will be properly conducted. The Commission may take enforcement action for reasons that would warrant refusal to issue a license on an original application. Accordingly, enforcement action may be taken regarding matters that raise issues of integrity, competence, fitness for duty, or other matters that may not necessarily be a violation of specific Commission requirements. And, in taking such enforcement action, the Commission may exercise independent discretion as to the standard of fitness for duty to be applied, depending on the circumstances of the case and the significance of the issue to maintaining reasonable assurance in the protection of the public health and safety in the use and possession of nuclear materials. For example, the Commission could take action to modify, revoke or suspend the license of an individually licensed person seen as not fit for duty on standards more strict than provided in Part 26, if necessary to protect the health and safety of the public or other workers. Similarly, the Commission could take appropriate action regarding a materials licensee where an employee was seen as endangering health and safety because he or she was not fit for duty.

Individuals who are not reliable and trustworthy, under the influence of any substance, or mentally or physically impaired in any way that adversely affects their ability to safely and competently perform their duties, shall not be licensed or permitted to perform responsible health and safety functions.

Supplemental Provisions of the Drug-Free Workplace Act of 1988

In promulgating this rule the Commission has taken note of the fact that the Congress of the United States has recently enacted Subtitle D of Title V of the Anti-Drug Abuse Act of 1988 (Pub. L. 100–690, enacted November 18, 1988), entitled, "The Drug-Free Workplace Act of 1988." This law requires any person being awarded a Government contract for property or services of a value of $25,000 or more to certify to the contracting agency that it will provide a drug free workplace for the performance of the contract. The precise requirements are in Section 5152 to 5160 of the Anti-Drug Abuse Act. The Commission has compared the requirements of the Drug-Free Workplace Act to the requirements of its rule on Fitness-For-Duty and finds no inconsistency. Any licensee implementing 10 CFR Part 26 who may also be subject to Subtitle D should have no difficulty meeting the supplemental provisions of the latter concerning notification of the contracting agency of convictions of onsite criminal drug activities [Section 5152(a)(1)(D) of the Anti-Drug Abuse Act] for those employees within the scope of a program meeting the provisions of 10 CFR Part 26. Whether or not any licensee subject to 10 CFR Part 26 is also subject to the Drug-Free Workplace Act of 1988 is a question that the Commission cannot answer. Each licensee will have to examine its own contractual relationships with agencies of the United States Government, if any, to ascertain if those contractual relationships are of a kind that call the Drug-Free Workplace Act into play.

Finding of No Significant Environmental Impact: Availability

An environmental assessment was included in the notice of the proposed rulemaking at 53 FR 36822. The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule is not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required.

Paperwork Reduction Act Statement

This final rule contains information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq). These requirements were approved by the Office of Management and Budget (OMB) at the proposed rule stage, approval number 3150–0146. The final rule adds new information collection requirements and increases records retention periods. Therefore, an amended clearance package is being submitted to OMB. The information collection requirements contained in the final rule will not become effective until they are approved by OMB.

Public reporting burden for this collection of information is estimated to average 8 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Records and Reports Management Branch (P-530), U.S. Nuclear Regulatory Commission, Washington, DC 20555; and to the Paperwork Reduction Project (3150-0146), Office of Management and Budget, Washington, DC 20503.

Regulatory Analysis

An analysis of the costs and benefits of the final rule is included in the backfit analysis described below.

Backfit Analysis

Several commenters stated that the NRC should justify the rulemaking under the provisions of § 50.109(a)(3). The NRC agrees, and finds that the rule will provide a substantial increase in the overall protection of public health and safety, and that the direct and indirect costs of implementation are justified in view of the increased protection.

The backfit analysis is available for inspection and copying for a fee at the NRC Public Document Room at 2120 L Street NW., Washington, DC 20555. Single copies may be obtained by writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555.

Regulatory Flexibility Act Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities. This new 10 CFR Part 26 applies to certain owners and operators of civilian nuclear power reactors and their contractors. The companies that own power reactor facilities do not fall within the scope of "small entities" set forth in the Regulatory Flexibility Act or the small business size standards set out in regulations issued by the Small Business Administration in 13 CFR Part 121. Any costs to the minor number of small entities affected, i.e., contractors, will apply only to those contractor employees working at the nuclear power reactors, and would probably be reimbursed through the contract.

List of Subjects

10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Civil penalty, Enforcement, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Violations, Waste treatment and disposal.

10 CFR Part 26

Alcohol abuse, Alcohol testing, Appeals, Chemical testing, Drug abuse, Drug testing, Employee assistance programs, Fitness for duty, Management actions, Nuclear power reactors, Protection of information, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C 553, the NRC is adopting a new 10 CFR Part 26, and amending 10 CFR Part 2.

PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

1. The authority citation for Part 2 continues to read in part as follows:

Authority: Sec. 161, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

2. Appendix C, Supplement VII, is amended by adding example 6 to paragraph A, examples 6, 7, and 8 to paragraph B, examples 6, 7, 8, and 9 to paragraph C, examples 4 and 5 to paragraph D, and example 4 to paragraph E to read as follows:

Appendix C—General Statement of Policy and Procedure for NRC Enforcement Actions

* * * * *

Supplement VII—Severity Categories

A. Severity I. * * *

6. Failure to substantially implement the required fitness-for-duty program.[18]

B. Severity II. * * *

6. Failure to remove an individual from unescorted access who has been involved in the sale, use, or possession of illegal drugs within the protected area or to take action for on duty misuse of alcohol, prescription drugs, or over-the-counter drugs;

7. Failure to test for cause when observed behavior within the protected area or credible information concerning activities within the protected area indicates possible unfitness for duty based on drug or alcohol use; or

8. Deliberate failure of the licensee's Employee Assistance Program to notify licensee's management when EAP's staff is aware that an individual's condition may adversely affect safety related activities.

C. Severity III. * * *

6. Failure to complete a suitable inquiry on the basis of 10 CFR Part 26, keep records concerning the denial of access, or respond to inquiries concerning such denials such that, as a result of the failure, a person previously denied access for fitness-for-duty reasons was improperly granted access;

7. Failure to take the required action for a person confirmed to have been tested positive for illegal drug use or take action for onsite alcohol use; not amounting to a Severity Level II violation;

8. Failure to assure, as required, that contractors or vendors have an effective fitness-for-duty program; or

9. Breakdown in the fitness-for-duty program involving a number of violations of the basic elements of the fitness-for-duty program that collectively reflect a significant lack of attention or carelessness towards meeting the objectives of 10 CFR 26.10.

D. Severity IV. * * *

4. Isolated failures to meet basic elements of the fitness-for-duty program not involving a Severity Level I, II, or III violation.

5. Failure to report acts of licensed operators or supervisors pursuant to 10 CFR 26.73.

E. Severity V. * * *

4. Minor violations of fitness-for-duty requirements.

3. Part 26 is added to 10 CFR Chapter I to read as follows:

PART 26—FITNESS FOR DUTY PROGRAMS

General Provisions

Sec.
26.1 Purpose.
26.2 Scope.
26.3 Definitions.
26.4 Interpretations.
26.6 Exemptions.
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General Performance Objectives

26.10 General performance objectives.

Program Elements and Procedures

26.20 Written policy and procedures.
26.21 Policy communications and awareness training.
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26.24 Chemical testing.
26.25 Employee assistance programs (EAP).
26.27 Management actions and sanctions to be imposed.
26.28 Appeals.
26.29 Protection of information.

Inspections, Records and Reports

26.70 Inspections.
26.71 Recordkeeping requirements.
26.73 Reporting requirements.

[18] The examples for violations for fitness-for-duty relate to violations of 10 CFR Part 26.

Sec.

Audits

26.80 Audits.

Enforcement

26.90 Violations.

Appendix A—Guidelines for Nuclear Power Plant Drug and Alcohol Testing Programs.

Authority: Secs. 53, 81, 103, 104, 107, 161, 68 Stat. 930, 935, 936, 937, 939, 948, as amended (42 U.S.C. 2073, 2111, 2112, 2133, 2134, 2137, 2201); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273) §§ 26.20, 26.21, 26.22, 26.23, 26.24, 26.25, 26.27, 26.28, 26.29 and 26.80 are issued under secs. 161b and i, 68 Stat. 948, and 949 as amended [42 U.S.C. 2201(b) and (i)]; 26.70, 26.71, and 26.73 are issued under sec. 161o, 68 Stat. 950, as amended [42 U.S.C. 2201(o)].

General Provisions

§ 26.1 Purpose.

This Part prescribes requirements and standards for the establishment and maintenance of certain aspects of fitness-for-duty programs and procedures by the licensed nuclear power industry.

§ 26.2 Scope.

(a) The regulations in this Part apply to licensees authorized to operate a nuclear power reactor. Each licensee shall implement a fitness-for-duty program which complies with this Part. The provisions of the fitness-for-duty program must apply to all persons granted unescorted access to protected areas, and to licensee, vendor, or contractor personnel required to physically report to a licensee's Technical Support Center (TSC) or Emergency Operations Facility (EOF) in accordance with licensee emergency plans and procedures. The regulations in this Part do not apply to NRC employees, or to law enforcement personnel or offsite emergency fire and medical response personnel while responding on-site.

(b) Certain regulations in this Part apply to licensees holding permits to construct a nuclear power plant. Each construction permit holder, with a plant under active construction, shall comply with sections 26.10, 26.20, 26.23, 26.70, and 26.73 of this part; shall implement a chemical testing program, including random tests; and shall make provisions for employee assistance programs, imposition of sanctions, appeal procedures, the protection of information, and recordkeeping.

(c) The requirements in this Part must be implemented by each licensee authorized to construct or operate a nuclear power reactor no later than (insert date 180 days after the effective date of the final rule).

§ 26.3 Definitions.

"Aliquot" means a portion of a specimen used for testing.

"Commission" means the Nuclear Regulatory Commission or its duly authorized representatives.

"Confirmatory test" means a second analytical procedure to identify the presence of a specific drug or drug metabolite which is independent of the initial screening test and which uses a different technique and chemical principle from that of the initial screening test in order to ensure reliability and accuracy. For determining blood alcohol levels, a "confirmatory test" means a second test using another breath alcohol analysis device. Further confirmation upon demand will be by gas chromatography analysis of blood.

"Confirmed positive test" means the result of a confirmatory test that has established the presence of drugs, drug metabolites, or alcohol in a specimen at or above the cut-off level, and that has been deemed positive by the Medical Review Officer (MRO) after evaluation. A "confirmed positive test" for alcohol can also be obtained as a result of a confirmation of blood alcohol levels with a second breath analysis without MRO evaluation.

"Contractor" means any company or individual with which the licensee has contracted for work or service to be performed inside the protected area boundary, either by contract, purchase order, or verbal agreement.

"Cut-off level" means the value set for designating a test result as positive.

"Follow-up testing" means chemical testing at unannounced intervals, to ensure that an employee is maintaining abstinence from the abuse of drugs or alcohol.

"Illegal drugs" means those drugs included in Schedules I through V of the Controlled Substances Act (CSA), but not when used pursuant to a valid prescription or when used as otherwise authorized by law.

"Initial or screening tests" means an immunoassay screen for drugs or drug metabolites to eliminate "negative" urine specimens from further consideration or the first breathalyzer test for alcohol. Initial screening may be performed at the licensee's testing facility; a second screen and confirmation testing for drugs or drug metabolites must be conducted by a HHS-certified laboratory.

"Medical Review Officer" means a licensed physician responsible for receiving laboratory results generated by an employer's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result together with his or her medical history and any other relevant biomedical information.

"Protected area" has the same meaning as in §73.2(g) of this chapter, an area encompassed by physical barriers and to which access is controlled.

"Random test" means a system of unannounced drug testing administered in a statistically random manner to a group so that all persons within that group have an equal probability of selection.

"Suitable inquiry" means best-effort verification of employment history for the past five years, but in no case less than three years, obtained through contacts with previous employers to determine if a person was, in the past, tested positive for illegal drugs, subject to a plan for treating substance abuse, removed from, or made ineligible for activities within the scope of 10 CFR Part 26, or denied unescorted access at any other nuclear power plant or other employment in accordance with a fitness-for-duty policy.

"Vendor" means any company or individual, not under contract to a licensee, providing services in protected areas.

§ 26.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this Part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 26.6 Exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this Part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

§ 26.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this Part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements

contained in this Part under control number 3150–0146.

(b) The approved information collection requirements contained in this Part appear in §§ 26.20, 26.21, 26.22, 26.23, 26.24, 26.27, 26.29, 26.70, 26.71, 26.73, 26.80 and Appendix A.

(c) The total burden for these recordkeeping requirements is estimated to be 313 hours per site per year. In implementing the recordkeeping requirements the affected licensee shall report to the Commission any comments concerning the accuracy of the estimate and any suggestions for reducing the burden.

General Performance Objectives

§ 26.10 General performance objectives.

Fitness-for-duty programs must:

(a) Provide reasonable assurance that nuclear power plant personnel will perform their tasks in a reliable and trustworthy manner and are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties;

(b) Provide reasonable measures for the early detection of persons who are not fit to perform activities within the scope of this Part; and

(c) Have a goal of achieving a drug-free workplace and a workplace free of the effects of such substances.

Program Elements and Procedures

§ 26.20 Written policy and procedures.

Each licensee subject to this Part shall establish and implement written policies and procedures designed to meet the general performance objectives and specific requirements of this Part. Each licensee shall retain a copy of the current written policy and procedures as a record until the Commission terminates each license for which the policy and procedures were developed and, if any portion of the policies and procedures are superseded, retain the superseded material for three years after each change. As a minimum, written policies and procedures must address fitness for duty through the following:

(a) An overall description of licensee policy on fitness for duty. The policy must address use of illegal drugs and abuse of legal drugs (e.g., alcohol, prescription and over-the-counter drugs). Written policy documents must be in sufficient detail to provide affected individuals with information on what is expected of them, and what consequences may result from lack of adherence to the policy. As a minimum, the written policy must prohibit the consumption of alcohol—

(1) Within an abstinence period of at least 5 hours preceding any scheduled working tour, and

(2) During the period of any working tour.

Licensee policy should also address other factors that could affect fitness for duty such as mental stress, fatigue and illness.

(b) A description of programs which are available to personnel desiring assistance in dealing with drug, alcohol, or other problems that could adversely affect the performance of activities within the scope of this Part.

(c) Procedures to be utilized in testing for drugs and alcohol, including procedures for protecting the employee and the integrity of the specimen, and the quality controls used to ensure the test results are valid and attributable to the correct individual.

(d) A description of immediate and follow-on actions which will be taken, and the procedures to be utilized, in those cases where employees, vendors, or contractors assigned to duties within the scope of this Part are determined to have been involved in the use, sale, or possession of illegal drugs; or to have consumed alcohol during the mandatory pre-work abstinence period, while on duty, or to excess prior to reporting to duty as demonstrated with a test that can be used to determine blood alcohol concentration.

(e) A procedure that will ensure that persons called in to perform an unscheduled working tour are fit to perform the task assigned. As a minimum, this procedure must—

(1) Require a statement to be made by a called-in person as to whether he or she has consumed alcohol within the length of time stated in the pre-duty abstinence policy;

(2) If alcohol has been consumed within this period, require a determination of fitness for duty by breath analysis or other means; and

(3) Require the establishment of controls and conditions under which a person who has been called-in can perform work, if necessary, although alcohol has been consumed. Consumption of alcohol during the abstinence period shall not by itself preclude a licensee from using individuals needed to respond to an emergency.

(f) The Commission may at any time review the licensee's written policy and procedures to assure that they meet the performance objectives of this Part.

§ 26.21 Policy communications and awareness training.

(a) Persons assigned to activities within the scope of this Part shall be provided with appropriate training to ensure they understand—

(1) Licensee policy and procedures, including the methods that will be used to implement the policy;

(2) The personal and public health and safety hazards associated with abuse of drugs and misuse of alcohol;

(3) The effect of prescription and over-the-counter drugs and dietary conditions on job performance and on chemical test results, and the role of the Medical Review Officer;

(4) Employee assistance programs provided by the licensee; and

(5) What is expected of them and what consequences may result from lack of adherence to the policy.

(b) Initial training must be completed prior to assignment to activities within the scope of this Part. Refresher training must be completed on a nominal 12 month frequency or more frequently where the need is indicated. A record of the training must be retained for a period of at least three years.

§ 26.22 Training of supervisors and escorts.

(a) Managers and supervisors of activities within the scope of this Part must be provided appropriate training to ensure they understand—

(1) Their role and responsibilities in implementing the program;

(2) The roles and responsibilities of others, such as the personnel, medical, and employee assistance program staffs;

(3) Techniques for recognizing drugs and indications of the use, sale, or possession of drugs;

(4) Behavioral observation techniques for detecting degradation in performance, impairment, or changes in employee behavior; and

(5) Procedures for initiating appropriate corrective action, to include referral to the employee assistance program.

(b) Persons assigned to escort duties shall be provided appropriate training in techniques for recognizing drugs and indications of the use, sale, or possession of drugs, techniques for recognizing aberrant behavior, and the procedures for reporting problems to supervisory or security personnel.

(c) Initial training must be completed prior to assignment of duties within the scope of this Part and within 3 months after initial supervisory assignment, as applicable. Refresher training must be completed on a nominal 12 month frequency, or more frequently where the

need is indicated. A record of the training must be retained for a period of at least three years.

§ 26.23 Contractors and vendors.

(a) All contractor and vendor personnel performing activities within the scope of this Part for a licensee must be subject to either the licensee's program relating to fitness for duty, or to a program, formally reviewed and approved by the licensee, which meets the requirements of this Part. Written agreements between licensees and contractors or vendors for activities within the scope of this Part must be retained for the life of the contract and will clearly show that—

(1) The contractor or vendor is responsible to the licensee for adhering to the licensee's fitness-for-duty policy, or maintaining and adhering to an effective fitness-for-duty program; which meets the standards of this Part; and

(2) Personnel having been denied access or removed from activities within the scope of this Part at any nuclear power plant for violations of a fitness-for-duty policy will not be assigned to work within the scope of this Part without the knowledge and consent of the licensee.

(b) Each licensee subject to this Part shall assure that contractors whose own fitness-for-duty programs are relied on by the licensee adhere to an effective program, which meets the requirements of this Part, and shall conduct audits pursuant to § 26.80 for this purpose.

§ 26.24 Chemical testing.

(a) To provide a means to deter and detect substance abuse, the licensee shall implement the following chemical testing programs for persons subject to this Part:

(1) Testing within 60 days prior to the initial granting of unescorted access to protected areas or assignment to activities within the scope of this Part.

(2) Unannounced tests imposed in a random manner. The tests must be administered so that a person completing a test is immediately eligible for another unannounced test. As a minimum, tests must be administered on a nominal weekly frequency and at various times during the day. Random testing shall be conducted at a rate equal to at least 100 percent of the workforce.

(3) Testing for-cause, i.e., as soon as possible following any observed behavior indicating possible substance abuse; after accidents involving a failure in individual performance resulting in personal injury, in a radiation exposure or release of radioactivity in excess of regulatory limits, or actual or potential substantial degradations of the level of safety of the plant if there is reasonable suspicion that the worker's behavior contributed to the event; or after receiving credible information that an individual is abusing drugs or alcohol.

(4) Follow-up testing on an unannounced basis to verify continued abstention from the use of substances covered under this Part.

(b) Testing for drugs and alcohol must at a minimum, conform to the "Guidelines for Nuclear Power Plant Drug and Alcohol Testing Programs," issued by the Nuclear Regulatory Commission and appearing in Appendix A to this rule, hereinafter referred to as the NRC Guidelines. Licensees, at their discretion, may implement programs with more stringent standards (e.g., lower cutoff levels, broader panel of drugs). All requirements in this Part apply to persons who fail a more stringent standard, but do not test positive under the NRC Guidelines; management actions must be the same as if the individual failed the NRC standards.

(c) Licensees shall test for all substances described in paragraph 2.1(a) of the NRC Guidelines. In addition, licensees may consult with local law enforcement authorities, hospitals, and drug counseling services to determine whether other substances with abuse potential are being used in the geographical locale of the facility and the local workforce. When appropriate, other substances so identified may be added to the panel of substances for testing. Appropriate cutoff limits must be established by the licensee for these substances.

(d) Licensees may conduct initial screening tests of an aliquot prior to forwarding selected specimens to a laboratory certified by the Department of Health and Human Services, provided the licensee's staff possesses the necessary training and skills for the tasks assigned, their qualifications are documented, and adequate quality controls are implemented. Quality control procedures for initial screening tests by a licensee's testing facility must include the processing of blind performance test specimens and the submission to the HHS-certified laboratory of a sampling of specimens initially tested as negative. Access to the results of preliminary tests must be limited to the licensee's testing staff, the Medical Review Officer, the Fitness-For-Duty Program Manager, and employee assistance program staff when appropriate.

(e) The Medical Review Officer's review of the test results must be completed and licensee management notified within 10 days of the initial presumptive positive screening test.

(f) All testing of specimens for urine drug testing, except onsite testing under paragraph (d) above, must be performed in a laboratory certified by the U.S. Department of Health and Human Services for that purpose consistent with its standards and procedures for certification. Except for suspect specimens submitted for special processing (Section 2.7(d) of Appendix A), all specimens sent to certified laboratories shall be subject to initial screening by the laboratory and all specimens screened as presumptively positive shall be subject to confirmation testing by the laboratory. Licensees shall submit blind performance test specimens to certified laboratories in accordance with the NRC Guidelines (Appendix A).

(g) Tests for alcohol must be administered by breath analysis using breath alcohol analyses devices meeting evidential standards described in Section 2.7(O)(3) of Appendix A. A breath alcohol content indicating a blood alcohol concentration of 0.04 percent or greater must be a positive test result. The confirmatory test for alcohol shall be done with another breath measurement instrument. Should the person demand further confirmation, the test must be a gas chromatography analysis of blood.

§ 26.25 Employee assistance programs (EAP).

Each licensee subject to this Part shall maintain an employee assistance program to strengthen fitness-for-duty programs by offering assessment, short-term counseling, referral services, and treatment monitoring to employees with problems that could adversely affect the performance of activities within the scope of this Part. Employee assistance programs should be designed to achieve early intervention and provide for confidential assistance. The employee assistance program staff shall inform licensee management when a determination has been made that any individual's condition constitutes a hazard to himself or herself or others (including those who have self-referred).

§ 26.27 Management actions and sanctions to be imposed.

(a) Prior to the initial granting of unescorted access to a protected area or the assignment to activities within the scope of this Part to any person, the licensee shall obtain a written statement from the individual as to whether activities within the scope of this Part were ever denied the individual. The

licensee shall complete a suitable inquiry on a best-efforts basis to determine if that person was, in the past, tested positive for drugs or use of alcohol that resulted in on-duty impairment, subject to a plan for treating substance abuse (except for self-referral for treatment), or removed from activities within the scope of this Part, or denied unescorted access at any other nuclear power plant in accordance with a fitness-for-duty policy. If such a record is established, the new assignment to activities within the scope of this Part or granting of unescorted access must be based upon a management and medical determination of fitness for duty and the establishment of an appropriate follow-up testing program, provided the restrictions of paragraph (b) of this section are observed. To meet this requirement, the identity of persons denied unescorted access or removed under the provisions of this Part and the circumstances for such denial or removal, including test results, will be made available in response to a licensee's, contractor's, or vendor's inquiry supported by a signed release from the individual. Failure to list reasons for removal or revocation of unescorted access shall be sufficient cause for denial of unescorted access. Temporary access provisions shall not be affected by this Part provided that the prospective worker passes a chemical test conducted according to the requirements of 26.24(a)(1).

(b) Each licensee subject to this Part shall, as a minimum, take the following actions. Nothing herein shall prohibit the licensee from taking more stringent action.

(1) Impaired workers, or those whose fitness may be questionable, shall be removed from activities within the scope of this Part, and may be returned only after determined to be fit to safely and competently perform activities within the scope of this Part.

(2) Lacking any other evidence to indicate the use, sale, or possession of illegal drugs onsite, a confirmed positive test result must be presumed to be an indication of offsite drug use. The first confirmed positive test must, as a minimum, result in immediate removal from activities within the scope of this Part for at least 14 days and referral to the EAP for assessment and counseling during any suspension period. Plans for treatment, follow-up, and future employment must be developed, and any rehabilitation program deemed appropriate must be initiated during such suspension period. Satisfactory management and medical assurance of the individual's fitness to adequately perform activities within the scope of this Part must be obtained before permitting the individual to be returned to these activities. Any subsequent confirmed positive test must result in removal from unescorted access to protected areas and activities within the scope of this Part for a minimum of three years from the date of removal.

(3) Any individual determined to have been involved in the sale, use, or possession of illegal drugs while within a protected area of any nuclear power plant must be removed from activities within the scope of this Part. The individual may not be granted unescorted access to protected areas or assigned to activities within the scope of this Part for a minimum of five years from the date of removal.

(4) Persons removed for periods of three years or more under the provisions of paragraphs (b) (2) and (3) of this section for the illegal sale, use or possession of drugs and who would have been removed under the current standards of a hiring licensee, may be granted unescorted access and assigned duties within the scope of this Part by a licensee subject to this Part only when the hiring licensee receives satisfactory medical assurance that the person has abstained from drugs for at least three years. Satisfactory management and medical assurance of the individual's fitness to adequately perform activities within the scope of this Part must be obtained before permitting the individual to perform activities within the scope of this Part. Any person granted unescorted access or whose access is reinstated under these provisions must be given unannounced follow-up tests at least once every month for four months and at least once every three months for the next two years and eight months after unescorted access is reinstated to verify continued abstinence from proscribed substances. Any confirmed use of drugs through this process or any other determination of subsequent involvement in the sale, use or possession of illegal substances must result in permanent denial of unescorted access.

(5) Paragraphs (b) (2), (3), and (4) of this section do not apply to alcohol, valid prescriptions, or over-the-counter drugs. Licensee sanctions for confirmed misuse of alcohol, valid prescription, and over-the-counter drugs shall be sufficient to deter abuse of legally obtainable substances as a substitute for abuse of proscribed drugs.

(c) Refusal to provide a specimen for testing and resignation prior to removal for violation of company fitness-for-duty policy concerning drugs must be recorded as removals for cause. These records must be retained for the purpose of meeting the requirements of § 26.27(a).

(d) If a licensee has a reasonable belief that an NRC employee may be under the influence of any substance, or otherwise unfit for duty, the licensee may not deny access but shall escort the individual. In any instance of this occurrence, the appropriate Regional Administrator must be notified immediately by telephone. During other than normal working hours, the NRC Operations Center must be notified.

§ 26.28 Appeals.

Each licensee subject to this Part, and each contractor or vendor implementing a fitness-for-duty program under the provisions of § 26.23, shall establish a procedure for licensee and contractor or vendor employees to appeal a positive alcohol or drug determination. The procedure must provide notice and an opportunity to respond and may be an impartial internal management review. A licensee review procedure need not be provided to employees of contractors or vendors when the contractor or vendor is administering his own alcohol and drug testing.

§ 26.29 Protection of information.

(a) Each licensee subject to this Part, who collects personal information on an individual for the purpose of complying with this Part, shall establish and maintain a system of files and procedures for the protection of the personal information. This system must be maintained until the Commission terminates each license for which the system was developed.

(b) Licensees, contractors, and vendors shall not disclose the personal information collected and maintained to persons other than assigned Medical Review Officers, other licensees or their authorized representatives legitimately seeking the information as required by this Part for unescorted access decisions and who have obtained a release from current or prospective employees or contractor personnel, NRC representatives, appropriate law enforcement officials under court order, the subject individual or his or her representative, or to those licensee representatives who have a need to have access to the information in performing assigned duties, including audits of licensee's, contractor's, and vendor's programs, to persons deciding matters on review or appeal, and to other persons pursuant to court order. This section does not authorize the licensee, contractor, or vendor to

withhold evidence of criminal conduct from law enforcement officials.

Inspections, Records, and Reports

§ 26.70 Inspections.

(a) Each licensee subject to this Part shall permit duly authorized representatives of the Commission to inspect, copy, or take away copies of its records and inspect its premises, activities, and personnel as may be necessary to accomplish the purposes of this Part.

(b) Written agreements between licensees and their contractors and vendors must clearly show that the—

(1) Licensee is responsible to the Commission for maintaining an effective fitness-for-duty program in accordance with this Part; and

(2) Duly authorized representatives of the Commission may inspect, copy, or take away copies of any licensee, contractor, or vendor's documents, records, and reports related to implementation of the licensee's, contractor's, or vendor's fitness-for-duty program under the scope of the contracted activities.

§ 26.71 Recordkeeping requirements.

Each licensee subject to this Part and each contractor and vendor implementing a licensee approved program under the provisions of § 26.23 shall—

(a) Retain records of inquiries conducted in accordance with § 26.27(a), that result in the granting of unescorted access to protected areas, until five years following termination of such access authorizations;

(b) Retain records of confirmed positive test results which are concurred in by the Medical Review Officer, and the related personnel actions for a period of at least five years;

(c) Retain records of persons made ineligible for three years or longer for assignment to activities within the scope of this Part under the provisions of § 26.27(b) (2), (3), (4) or (c), until the Commission terminates each license under which the records were created; and

(d) Collect and compile fitness-for-duty program performance data on a standard form and submit this data to the Commission within 60 days of the end of each 6 month reporting period (January-June and July-December). The data for each site (corporate and other support staff locations may be separately consolidated) shall include: random testing rate; drugs tested for and cut-off levels, including results of tests using lower cut-off levels and tests for other drugs; workforce populations tested; numbers of tests and results by population and type of test (i.e., pre-badging, random, for-cause, etc.); substances identified; summary of management actions; and a list of events reported. The data must be analyzed and appropriate actions taken to correct program weaknesses. The data and analysis must be retained for three years.

§ 26.73 Reporting requirements.

(a) Each licensee subject to this Part shall inform the Commission of significant fitness-for-duty events including:

(1) Sale, use, or possession of illegal drugs within the protected area and,

(2) Any acts by any person licensed under 10 CFR Part 55 to operate a power reactor or by any supervisory personnel assigned to perform duties within the scope of this Part—

(i) Involving the sale, use, or possession of a controlled substance,

(ii) Resulting in confirmed positive tests on such persons,

(iii) Involving use of alcohol within the protected area, or

(iv) Resulting in a determination of unfitness for scheduled work due to the consumption of alcohol.

(b) Notifications must be made to the NRC Operations Center by telephone within 24 hours of the discovery of the event by the licensee.

(c) Fitness-for-duty events shall be reported under this section rather than reported under the provisions of § 73.71.

(d) By (insert date 180 days after the effective date of the final rule) each licensee shall certify to the NRC that it has implemented a fitness-for-duty program that meets the requirements of 10 CFR Part 26. The certification shall describe any licensee cut-off levels more stringent than those imposed by this Part.

Audits

§ 26.80 Audits.

(a) Each licensee subject to this Part shall audit the fitness-for-duty program nominally every 12 months. In addition, audits must be conducted, nominally every 12 months, of those portions of fitness-for-duty programs implemented by contractors and vendors. Licensees may accept audits of contractors and vendors conducted by other licensees and need not re-audit the same contractor or vendor for the same period of time. Each sharing utility shall maintain a copy of the audit report, to include findings, recommendations and corrective actions. Licensees retain responsibility for the effectiveness of contractor and vendor programs and the implementation of appropriate corrective action.

(b) Audits must focus on the effectiveness of the program and be conducted by individuals qualified in the subject(s) being audited, and independent of both fitness-for-duty program management and personnel directly responsible for implementation of the fitness-for-duty program.

(c) The result of the audit, along with recommendations, if any, must be documented and reported to senior corporate and site management. The resolution of the audit findings and corrective actions must be documented. These documents must be retained for three years. NRC Guidelines require licensee audits of HHS-certified laboratories as described in Appendix A.

Enforcement

§ 26.90 Violations.

(a) An injunction or other court order may be obtained to prohibit a violation of any provision of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974; or

(3) Any regulation or order issued under these Acts.

(b) A court order may be obtained for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act of 1954, for violations of—

(1) Section 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Act;

(2) Section 206 of the Energy Reorganization Act of 1974;

(3) Any rule, regulation, or order issued under these Sections;

(4) Any term, condition, or limitation of any license issued under these Sections; or

(5) Any provisions for which a license may be revoked under section 186 of the Atomic Energy Act of 1954.

(c) Any person who willfully violates any provision of the Atomic Energy Act of 1954, as amended, or any regulation or order issued under the requirements of the Act, include regulations under this Part, may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

Appendix A—Guidelines for Nuclear Power Plant Drug and Alcohol Testing Programs

Subpart A—General

1.1 Applicability
1.2 Definitions

Subpart B—Scientific and Technical Requirements

2.1 The Substances
2.2 General Administration of Testing

Subpart A—General

1.1 Applicability.

(1) These guidelines apply to licensees authorized to operate nuclear power reactors.

(2) Licensees may set more stringent cut-off levels than specified herein or test for substances other than specified herein and shall inform the Commission of such deviation within 60 days of implementing such change. Licensees may not deviate from the provisions of these guidelines without the written approval of the Commission.

(3) Only laboratories which are HHS-certified are authorized to perform urine drug testing for NRC licensees, vendors, and licensee contractors.

1.2 Definitions.

For the purposes of this part, the following definitions apply:

"Aliquot." A portion of a specimen used for testing.

"BAC." Blood alcohol concentration (BAC), which can be measured directly from blood or derived from a measure of the concentration of alcohol in a breath specimen, is a measure of the mass of alcohol in a volume of blood such that an individual with 100 mg of alcohol per 100 ml of blood has a BAC of 0.10 percent.

"Commission." The U.S. Nuclear Regulatory Commission or its duly authorized representatives.

"Chain-of-custody." Procedures to account for the integrity of each specimen by tracking its handling and storage from the point of specimen collection to final disposition of the specimen.

"Collection site." A place designated by the licensee where individuals present themselves for the purpose of providing a specimen of their urine, breath, and/or blood to be analyzed for the presence of drugs or alcohol.

"Collection site person." A person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the specimen(s) provided by those individuals. A collection site person shall have successfully completed training to carry out this function or shall be a licensed medical professional or technician who is provided instructions for collection under this part and certifies completion as required herein. In any case where: (a) a collection is observed or (b) collection is monitored by nonmedical personnel, the collection site person must be a person of the same gender as the donor.

"Confirmatory test." A second analytical procedure to identify the presence of a specific drug or drug metabolite which is independent of the initial screening test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability and accuracy. (At this time gas chromatography/mass spectrometry [GC/MS] is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, phencyclidine). For determining blood alcohol levels, a "confirmatory test" means a second test using another breath alcohol analysis device. Further confirmation upon demand will be by gas chromatography analysis of blood.

"Confirmed positive test." The result of a confirmatory test that has established the presence of drugs, drug metabolites, or alcohol in a specimen at or above the cut-off level, and that has been deemed positive by the Medical Review Officer (MRO) after evaluation. A "confirmed positive test" for alcohol can also be obtained as a result of a confirmation of blood alcohol levels with a second breath analysis without MRO evaluation.

"HHS-certified laboratory." A urine and blood testing laboratory that maintains certification to perform drug testing under the Department of Health and Human Services (HHS) "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (53 FR 11970).

"Illegal drugs." Those drugs included in Schedules I through V of the Controlled Substances Act (CSA), but not when used pursuant to a valid prescription or when used as otherwise authorized by law.

"Initial or screening test." An immunoassay screen for drugs or drug metabolites to eliminate "negative" urine specimens from further consideration or the first breathalyzer test for alcohol.

"Licensee's testing facility." A drug testing facility operated by the licensee or one of its vendors or contractors to perform the initial testing of urine samples and to perform initial breath tests for alcohol. Such a testing facility is optional and not required to maintain HHS certification under this part.

"Medical Review Officer." A licensed physician responsible for receiving laboratory results generated by an employer's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result together with his or her medical history and any other relevant biomedical information.

"Permanent record book." A permanently bound book in which identifying data on each specimen collected at a collection site are permanently recorded in the sequence of collection.

"Reason to believe." Reason to believe that a particular individual may alter or substitute the urine specimen.

"Split sample." A portion of a urine specimen that may be stored by the licensee to be tested in the event of appeal.

Subpart B—Scientific and Technical Requirements

2.1 The Substances.

(a) Licensees shall, as a minimum, test for marijuana, cocaine, opiates, amphetamines, phencyclidine, and alcohol for pre-access, for-cause, random, and follow-up tests.

(b) Licensees may test for any illegal drugs during a for-cause test, or analysis of any specimen suspected of being adulterated or diluted through hydration or other means.

(c) Licensees shall establish rigorous testing procedures that are consistent with the intent of these guidelines for any other drugs not specified in these guidelines for which testing is authorized under 10 CFR 26, so that the appropriateness of the use of these substances can be evaluated by the Medical Review Officer to ensure that individuals granted unescorted access are fit for maintaining access to and for performing duties in protected areas.

(d) Specimens collected under NRC regulations requiring compliance with this part may only be designated or approved for testing as described in this part and shall not be used to conduct any other analysis or test without the permission of the tested individual.

(e) This section does not prohibit procedures reasonably incident to analysis of a specimen for controlled substances (e.g., determination of pH on tests for specific gravity, creatinine concentration, or presence of adulterants).

2.2 General Administration of Testing.

The licensee testing facilities and HHS-certified laboratories described in this part shall develop and maintain clear and well-documented procedures for collection, shipment, and accession of urine and blood specimens under this part. Such procedures shall include, as a minimum, the following:

(a) Use of a chain-of-custody form. The original shall accompany the specimen to the HHS-certified laboratory. A copy shall accompany any split sample. The form shall be a permanent record on which is retained identity data (or codes) on the employee and information on the specimen collection process and transfers of custody of the specimen.

(b) Use of a tamperevident sealing system designed in a manner such that the specimen container top can be sealed against undetected opening, the container can be identified with a unique identifying number identical to that appearing on the chain-of-custody form, and space has been provided to initial the container affirming its identity. For purposes of clarity, this requirement assumes use of a system made up of one or more pre-printed labels and seals (or a unitary label/seal), but use of other, equally effective technologies is authorized.

(c) Use of a shipping container in which one or more specimens and associated paperwork may be transferred and which can be sealed and initialled to prevent undetected tampering.

(d) Written procedures, instructions, and training shall be provided as follows:

(1) Licensee collection site procedures and training of collection site personnel shall

clearly emphasize that the collection site person is responsible for maintaining the integrity of the specimen collection and transfer process, carefully ensuring the modesty and privacy of the individual tested, and is to avoid any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

(2) A non-medical collection site person shall receive training in compliance with this appendix and shall demonstrate proficiency in the application of this appendix prior to serving as a collection site person. A medical professional, technologist, or technician licensed or otherwise approved to practice in the jurisdiction in which collection occurs may serve as a collection site person if that person is provided the instructions described in 2.2(3) and performs collections in accordance with those instructions.

(3) Collection site persons shall be provided with detailed, clearly-illustrated, written instructions on the collection of specimens in compliance with this part. Individuals subject to testing shall also be provided standard written instructions setting forth their responsibilities.

(4) The option to provide a blood specimen for confirmatory analysis following a positive breath test shall be specified in the written instructions provided to individuals tested. The instructions shall also state that failure to request a confirmatory blood test indicates that the individual accepts the breath test results.

2.3 Preventing Subversion of Testing.

Licensees shall carefully select and monitor persons responsible for administering the testing program (e.g., collection site persons, laboratory technicians, specimen couriers, and those selecting and notifying personnel to be tested), based upon the highest standards for honesty and integrity, and shall implement measures to ensure that these standards are maintained. As a minimum, these measures shall ensure that the integrity of such persons is not compromised or subject to efforts to compromise due to personal relationships with any individuals subject to testing.

As a minimum:

(1) Supervisors, co-workers, and relatives of the individual being tested shall not perform any collection, assessment, or evaluation procedures.

(2) Appropriate background checks and psychological evaluations shall be completed prior to assignment of any tasks associated with the administration of the program, and shall be conducted at least once every three years.

(3) Persons responsible for administering the testing program shall be subjected to a behavioral observation program designed to assure that they continue to meet the highest standards for honesty and integrity.

2.4 Specimen Collection Procedures.

(a) "Designation of Collection Site." Each drug testing program shall have one or more designated collection sites which have all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and shipping or transportation of urine or blood specimens to a drug testing laboratory. A properly equipped mobile facility that meets the requirements of this part is an acceptable collection site.

(b) "Collection Site Person." A collection site person shall have successfully completed training to carry out this function. In any case where the collection of urine is observed, the collection site person must be a person of the same gender as the donor. Persons drawing blood shall be qualified to perform that task.

(c) "Security." The purpose of this paragraph is to prevent unauthorized access which could compromise the integrity of the collection process or the specimen. Security procedures shall provide for the designated collection site to be secure. If a collection site facility cannot be dedicated solely to drug and alcohol testing, the portion of the facility used for testing shall be secured during that testing.

(1) A facility normally used for other purposes, such as a public rest room or hospital examining room, may be secured by visual inspection to ensure other persons are not present, and that undetected access (e.g., through a rear door not in the view of the collection site person) is impossible. Security during collection may be maintained by effective restriction of access to collection materials and specimens. In the case of a public rest room, the facility must be posted against access during the entire collection procedure to avoid embarrassment to the individual or distraction of the collection site person.

(2) If it is impractical to maintain continuous physical security of a collection site from the time the specimen is presented until the sealed container is transferred for shipment, the following minimum procedures shall apply: The specimen shall remain under the direct control of the collection site person from delivery to its being sealed in a mailer or secured for shipment. The mailer shall be immediately mailed, maintained in secure storage, or remain until mailed under the personal control of the collection site person. These minimum procedures shall apply to the mailing of specimens to licensee testing facilities from collection sites (except where co-located) as well as to the mailing of specimens to HHS-certified laboratories. As an option, licensees may ship several specimens via courier in a locked or sealed shipping container.

(d) "Chain-of-Custody." Licensee chain-of-custody forms shall be properly executed by authorized collection site personnel upon receipt of specimens. Handling and transportation of urine and blood specimens from one authorized individual or place to another shall always be accomplished through chain-of-custody procedures. Every effort shall be made to minimize the number of persons handling the specimens.

(e) "Access to Authorized Personnel Only." No unauthorized personnel shall be permitted in any part of the designated collection site where specimens are collected or stored. Only the collection site person may handle specimens prior to their securement in the mailing or shipping container or monitor or observe specimen collection (under the conditions specified in this part). In order to promote security of specimens, avoid distraction of the collection site person, and ensure against any confusion in the identification of specimens, a collection site person shall conduct only one collection procedure at any given time. For this purpose, a collection procedure is complete when the specimen container has been sealed and initialed, the chain-of-custody form has been executed, and the individual has departed the collection site.

(f) "Privacy." Procedures for collecting urine specimens shall allow individual privacy unless there is reason to believe that a particular individual may alter or substitute the specimen to be provided. For purposes of this appendix the following circumstances are the exclusive grounds constituting a reason to believe that the individual may alter or substitute a urine specimen:

(1) The individual has presented a urine specimen that falls outside the normal temperature range, and the individual declines to provide a measurement of oral body temperature by sterile thermometer, as provided in paragraph (g)(14) of this appendix, or the oral temperature does not equal or exceed that of the specimen.

(2) The last urine specimen provided by the individual (i.e., on a previous occasion) was determined by the laboratory to have a specific gravity of less than 1.003 or a creatinine concentration below .2 g/L.

(3) The collection site person observes conduct clearly and unequivocally indicating an attempt to substitute or adulterate the sample (e.g., substitute urine in plain view, blue dye in specimen presented, etc.).

(4) The individual has previously been determined to have used a substance inappropriately or without medical authorization and the particular test is being conducted as a part of a rehabilitation program or on return to service after evaluation and/or treatment for a confirmed positive test result.

(g) "Integrity and Identity of Specimens." Licensees shall take precautions to ensure that a urine specimen is not adulterated or diluted during the collection procedure, that a blood sample or breath exhalent tube cannot be substituted or tampered with, and that the information on the specimen container and in the record book can identify the individual from whom the specimen was collected. The following minimum precautions shall be taken to ensure that authentic specimens are obtained and correctly identified:

(1) To deter the dilution of urine specimens at the collection site, toilet bluing agents shall be placed in toilet tanks wherever possible, so the reservoir of water in the toilet bowl always remains blue. There shall be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs. If there is another source of water in the enclosure, it shall be effectively secured or monitored to ensure it is not used (undetected) as a source for diluting the specimen.

(2) When an individual arrives at the collection site for a urine or breath test, the collection site person shall ensure that the individual is positively identified as the person selected for testing (e.g., through presentation of photo identification or identification by the employer's representative). If the individual's identity

cannot be established, the collection site person shall not proceed with the collection.

(3) If the individual fails to arrive for a urine or breath test at the assigned time, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(4) After the individual has been positively identified, the collection site person shall ask the individual to sign a consent-to-testing form and to list all of the prescription medications and over-the-counter preparations that he or she can remember using within the past 30 days.

(5) The collection site person shall ask the individual to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the individual's urine, breath, or blood specimen. The collection site person shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments outside of the room in which the blood, breath, or urine sample is collected. The individual may retain his or her wallet.

(6) The individual shall be instructed to wash and dry his or her hands prior to urination.

(7) After washing hands prior to urination, the individual shall remain in the presence of the collection site person and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent or any other materials which could be used to adulterate the urine specimen.

(8) The individual may provide his/her urine specimen in the privacy of a stall or otherwise partitioned areas that allows for individual privacy.

(9) The collection site person shall note any unusual behavior or appearance in the permanent record book and on the chain-of-custody form.

(10) In the exceptional event that a designated collection site is inaccessible and there is an immediate requirement for urine specimen collection (e.g., an accident investigation), a public or on-site rest room may be used according to the following procedures. A collection site person of the same gender as the individual shall accompany the individual into the rest room which shall be made secure during the collection procedure. If possible, a toilet bluing agent shall be placed in the bowl and any accessible toilet tank. The collection site person shall remain in the rest room, but outside the stall, until the specimen is collected. If no bluing agent is available to deter specimen dilution, the collection site person shall instruct the individual not to flush the toilet until the specimen is delivered to the collection site person. After the collection site person has possession of the specimen, the individual will be instructed to flush the toilet and to participate with the collection site person in completing the chain-of-custody procedures.

(11) Upon receiving a urine specimen from the individual, the collection site person shall determine that it contains at least 60 milliliters of urine. If there is less than 60 milliliters of urine in the container, additional urine shall be collected in a separate container to reach a total of 60 milliliters. (The temperature of the partial specimen in each separate container shall be measured in accordance with paragraph (f)(13) of this section, and the partial specimens shall be combined in one container.) The individual may be given a reasonable amount of liquid to drink for this purpose (e.g., a glass of water). If the individual fails for any reason to provide 60 milliliters of urine, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(12) After the urine specimen has been provided and submitted to the collection site person, the individual shall be allowed to wash his or her hands.

(13) Immediately after the urine specimen is collected, the collection site person shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement is critical and in no case shall exceed 4 minutes.

(14) If the temperature of a urine specimen is outside the range of 32.5°–37.7 °C/90.5°–99.8 °F, that is a reason to believe that the individual may have altered or substituted the specimen, and another specimen shall be collected under direct observation of a same gender collection site person and both specimens shall be forwarded to the laboratory for testing. An individual may volunteer to have his or her oral temperature taken to provide evidence to counter the reason to believe the individual may have altered or substituted the specimen caused by the specimen's temperature falling outside the prescribed range.

(15) Immediately after a urine specimen is collected, the collection site person shall also inspect the specimen to determine its color and look for any signs of contaminants. Any unusual findings shall be noted in the permanent record book.

(16) All urine specimens suspected of being adulterated or found to be diluted shall be forwarded to the laboratory for testing.

(17) Whenever there is reason to believe that a particular individual may alter or substitute the urine specimen to be provided, a second specimen shall be obtained as soon as possible under the direct observation of a same gender collection site person. Where appropriate, measures will be taken to prevent additional hydration.

(18) Alcohol breath tests shall be delayed at least 15 minutes if any source of mouth alcohol (e.g., breath fresheners) or any other substances are ingested (e.g., eating, smoking, regurgitation of stomach contents from vomiting or burping). The collection site person shall ensure that each breath specimen taken comes from the end, rather than the beginning, of the breath expiration. For each screening test, two breath specimens shall be collected from each individual no less than two minutes apart and no more than 10 minutes apart. The test results shall be considered accurate if the result of each measurement is within plus or minus 10 percent of the average of the two measurements. If the two tests do not agree, the breath tests shall be repeated on another evidential-grade breath analysis device. Confirmatory testing is accomplished by repeating the above procedure on another evidential-grade breath analysis device.

(19) If the alcohol breath tests indicates that the individual is positive for a BAC at or above the 0.04 percent cut-off level, the individual may request a confirmatory blood test, at his or her discretion. All vacuum tube and needle assemblies used for blood collection shall be factory-sterilized. The collection site person shall ensure that they remain properly sealed until used. Antiseptic swabbing of the skin shall be performed with a nonethanol antiseptic. Sterile procedures shall be followed when drawing blood and transferring the blood to a storage container; in addition, the container must be sterile and sealed.

(20) Both the individual being tested and the collection site person shall keep urine and blood specimens in view at all times prior to their being sealed and labeled. If a urine specimen is split (as described in Section 2.7(j)) and if any specimen is transferred to a second container, the collection site person shall request the individual to observe the splitting of the urine sample or the transfer of the specimen and the placement of the tamperevident seal over the container caps and down the sides of the containers.

(21) The collection site person and the individual shall be present at the same time during procedures outlined in paragraphs (h) through (j) of this section.

(22) The collection site person shall place securely on each container an identification label which contains the date, the individual's specimen number, and any other identification information provided or required by the drug testing program. If separate from the labels, the tamperevident seals shall also be applied.

(23) The individual shall initial the identification labels on the specimen containers for the purpose of certifying that it is the specimen collected from him or her.

(i) The individual shall be asked to read and sign a statement on either the chain-of-custody form or in the permanent record book certifying that the specimens identified as having been collected from him or her are in fact the specimen he or she provided.

(ii) The individual shall be provided an opportunity to set forth on the urine chain-of-custody form information concerning medications taken or administered in the past 30 days.

(24) The collection site person shall enter in the permanent record book all information identifying the specimens. The collection site person shall sign the permanent record book next to the identifying information.

(25) A higher level supervisor in the drug testing program shall review and concur in advance with any decision by a collection site person to obtain a urine specimen under the direct observation of a same gender collection site person based on a reason to believe that the individual may alter or substitute the specimen to be provided.

(26) The collection site person shall complete the chain-of-custody forms for both the aliquot and the split sample, if collected, and shall certify proper completion of the collection.

(27) The specimens and chain-of-custody forms are now ready for transfer to the laboratory or the licensee's testing facility. If the specimens are not immediately prepared for shipment, they shall be appropriately safeguarded during temporary storage.

(28) While any part of the above chain-of-custody procedures is being performed, it is essential that the specimens and custody documents be under the control of the involved collection site person. The collection site person shall not leave the collection site in the interval between presentation of the specimen by the individual and securement of the samples with identifying labels bearing the individual's specimen identification numbers and seals initialled by the individual. If the involved collection site person leaves his or her work station momentarily, the specimens and chain-of-custody forms shall be taken with him or her or shall be secured. If the collection site person is leaving for an extended period of time, the specimens shall be packaged for transfer to the laboratory before he or she leaves the site.

(h) "Collection Control." To the maximum extent possible, collection site personnel shall keep the individual's specimen containers within sight both before and after the individual has urinated or provided a breath or blood sample. After the specimen is collected and whenever urine specimens are split, they shall be properly sealed and labeled. A chain-of-custody form shall be used for maintaining control and accountability of each specimen from the point of collection to final disposition of the specimen. The date and purpose shall be documented on the chain-of-custody form each time a specimen is handled or transferred, and every individual in the chain of custody shall be identified. Every effort shall be made to minimize the number of persons handling specimens.

(i) "Transportation to Laboratory or Testing Facility." Collection site personnel shall arrange to transfer the collected specimens to the drug testing laboratory or licensee testing facility. To transfer specimens off-site for initial screening and for a second screen and confirmatory analysis of presumptive positive specimens and for transferring suspect specimens to a laboratory for analysis under special processing [Section 2.7(d)], the specimens shall be placed in containers designed to minimize the possibility of damage during shipment (e.g., specimen boxes, padded mailers, or bulk shipping containers with that capability) and those containers shall be securely sealed to eliminate the possibility of undetected tampering. On the tape sealing the container, the collection site person shall sign and enter the date specimens were sealed in the containers for shipment. The collection site personnel shall ensure that the chain-of-custody documentation is attached to each container sealed for shipment to the drug testing laboratory.

(j) "Failure to Cooperate." If the individual refuses to cooperate with the urine collection or breath analysis process (e.g., refusal to provide a complete specimen, complete paperwork, initial specimen), then the collection site person shall inform the Medical Review Officer and shall document the non-cooperation in the permanent record book and on the specimen custody and control form. The Medical Review Officer shall report the failure to cooperate to the appropriate management. The provision of blood specimens for use to confirm a positive breath test for alcohol shall be entirely voluntary, at the individual's discretion. In the absence of a voluntary blood test the second positive breath test shall be considered a confirmed positive.

2.5. HHS-certified Laboratory Personnel.

(a) "Day-to-Day Management of the HHS-certified Laboratories."

(1) The HHS-certified laboratory shall have a qualified individual to assume professional, organizational, educational, and administrative responsibility for the laboratories' drug testing facilities.

(2) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are:

(i) Certification as a laboratory director by the appropriate State in forensic or clinical laboratory toxicology; or

(ii) A Ph.D. in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology, or

(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology, and

(iv) In addition to the requirements in (i), (ii), and (iii) above, minimum qualifications also require:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse; and

(B) Appropriate training and/or experience in forensic applications of analytical toxicology, e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors which qualify the individual as an expert witness in forensic toxicology.

(3) This individual shall be engaged in and responsible for the day-to-day management of the testing laboratory even where another individual has overall responsibility for an entire multispecialty laboratory.

(4) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of their testing laboratories. He or she shall assure the continued competency of laboratory personnel by documenting their inservice training, reviewing their work performance, and verifying their skills.

(5) This individual shall be responsible for the laboratory's having a procedure manual which is complete, up-to-date, available for personnel performing tests, and followed by those personnel. The procedure manual shall be reviewed, signed, and dated by this responsible individual whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the laboratory. Copies of all procedures and dates on which they are in effect shall be maintained. (Specific contents of the procedure manual are described in Section 2.7(0) of this appendix).

(6) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; for maintaining acceptable analytical performance for all controls and standards; for maintaining quality control testing; and for assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(7) This individual shall be responsible for taking all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual shall ensure that test results are not reported until all corrective actions have been taken and he or she can assure that the test results provided are accurate and reliable.

(b) "Test Validation." The laboratory's urine drug testing facility shall have a qualified individual(s) who reviews all pertinent data and quality control results in order to attest to the validity of the laboratory's test reports. A laboratory may designate more than one person to perform this function. This individual(s) may be any employee who is qualified to be responsible for day-to-day management or operation of the drug testing laboratory.

(c) "Day-to-Day Operations and Supervision of Analysts." The laboratory's urine drug testing facility shall have an individual to be responsible for day-to-day operations and to supervise the technical analysts. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; maintenance of chain-of-custody; and proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

(d) "Other Personnel." Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(e) "Training." The laboratory's testing program shall make available continuing education programs to meet the needs of laboratory personnel.

(f) "Files." Laboratory personnel files shall include: résumé of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; and results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate.

2.6 Licensee Testing Facility Personnel.

(a) "Day-to-Day Management of Operations." Any licensee testing facility shall have an individual to be responsible for day-to-day operations and to supervise the

testing technicians. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the licensee testing facility, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; and proper remedial actions to be taken in response to detecting aberrant test or quality control results.

(b) "Other Personnel." Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(c) "Files." Licensees' testing facility personnel files shall include: résumé of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate and appropriate data to support determinations of honesty and integrity conducted in accordance with Section 2.3 of this appendix.

2.7 Laboratory and Testing Facility Analysis Procedures.

(a) "Security and Chain-of-Custody."

(1) HHS-certified drug testing laboratories and any licensee testing facility shall be secure at all times. They shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory processes or to areas where records and split samples are stored. Access to these secured areas shall be limited to specifically authorized individuals whose authorization is documented. All authorized visitors and maintenance and service personnel shall be escorted at all times in the HHS-certified laboratory and in the licensee's testing facility. Documentation of individuals accessing these areas, dates, and times of entry and purpose of entry must be maintained.

(2) Laboratories and testing facilities shall use chain-of-custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of specimens. The date and purpose shall be documented on an appropriate chain-of-custody form each time a specimen is handled or transferred, and every individual in the chain shall be identified. Accordingly, authorized technicians shall be responsible for each urine specimen or aliquot in their possession and shall sign and complete chain-of-custody forms for those specimens or aliquots as they are received.

(b) "Receiving."

(1) When a shipment of specimens is received, laboratory and licensee's testing facility personnel shall inspect each package for evidence of possible tampering and compare information on specimen containers within each package to the information on the accompanying chain-of-custody forms. Any direct evidence of tampering or discrepancies in the information on specimen containers and the licensee's chain-of-custody forms attached to the shipment shall be reported within 24 hours to the licensee, in the case of HHS-certified laboratories, and shall be noted on the laboratory's chain-of-custody form which shall accompany the specimens while they are in the laboratory's possession. Indications of tampering with specimens at a testing facility operated by a licensee shall be reported within 8 hours to senior licensee management.

(2) Specimen containers will normally be retained within the laboratory's or testing facility's accession area until all analyses have been completed. Aliquots and the chain-of-custody forms shall be used by laboratory or testing facility personnel for conducting initial and confirmatory tests, as appropriate.

(c) "Short-Term Refrigerated Storage." Specimens that do not receive an initial test within 7 days of arrival at the laboratory or are not shipped within 6 hours from the licensee's testing facility and any retained split samples shall be placed in secure refrigeration units. Temperatures shall not exceed 6 °C. Emergency power equipment shall be available in case of prolonged power failure.

(d) "Specimen Processing." Urine specimens identified as presumptive positive by a licensee's testing facility shall be shipped to an HHS-certified laboratory for testing. Laboratory facilities for drug testing will normally process urine specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its workload. When conducting either initial or confirmatory tests at either the licensee's testing facility or an HHS-certified laboratory, every batch shall contain an appropriate number of standards for calibrating the instrumentation and a minimum of 10 percent controls. Both quality control and blind performance test samples shall appear as ordinary samples to laboratory analysts. Special processing may be conducted to analyze specimens suspected of being adulterated or diluted (including hydration). Any evidence of adulteration or dilution, and any detected trace amounts of drugs or metabolites, shall be reported to the Medical Review Officer.

(e) "Preliminary Initial Test."

(1) For the analysis of urine specimens, any preliminary test performed by a licensee's testing facility and the initial screening test performed by a HHS-certified laboratory shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The initial test of breath for alcohol performed at the collection site shall use a breath measurement device which meets the requirements of Section 2.7(o)(3). The following initial cut-off levels shall be used when screening specimens to determine whether they are negative for the indicated substances:

Initial test cut-off level (ng/ml)	
Marijuana metabolites	100
Cocaine metabolites	300
Opiate metabolites	300*
Phencyclidine	25
Amphetamines	1,000
Alcohol	0.04% BAC

*25 ng/ml is immunoassay specific for free morphine.

In addition, licensees may specify more stringent cutoff levels. Results shall be reported for both levels in such cases.

(2) The list of substances to be tested and the cut-off levels are subject to change by the NRC in response to industry experience and changes to the HHS Guidelines made by the Department of Health and Human Services as advances in technology, additional experience, or other considerations warrant the inclusion of additional substances and other concentration levels.

(f) "Confirmatory Test."

(1) Specimens which test negative as a result of this second screening shall be reported as negative to the licensee and will not be subject to any further testing unless special processing of the specimen is desired because adulteration or dilution is suspected.

(2) All urine samples identified as presumptive positive on the screening test performed by a HHS-certified laboratory shall be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques at the cut-off values listed in this paragraph for each drug, and at the cut-off values required by the licensee's unique program, where differences exist. All confirmations shall be by quantitative analysis. Concentrations which exceed the linear region of the standard curve shall be documented in the laboratory record as "greater than highest standard curve value."

Confirmatory test cut-off level (ng/ml)	
Marijuana metabolite	15*
Cocaine metabolite	150**
Opiates:	
Morphine	300
Codeine	300
Phencyclidine	25
Amphetamines:	
Amphetamine	500
Methamphetamine	500
Alcohol	0.04% BAC

*Delta-9-tetrahydrocannabinol-9-carboxylic acid.

**Benzoylecgonine.

In addition, licensees may specify more stringent cut-off levels. Results shall be reported for both levels in such cases.

(3) The analytic procedure for confirmatory analysis of blood specimens voluntarily provided by individuals testing positive for alcohol on a breath test shall be gas chromatography analysis.

(4) The list of substances to be tested and the cut-off levels are subject to change by the NRC in response to industry experience and changes to the HHS Guidelines made by the Department of Health and Human Services as advances in technology, additional experience, or other considerations warrant the inclusion of additional substances and other concentration levels.

(5) Confirmatory tests for opiates shall include a test for 6-monoacetylmorphine (MAM) if the screening test is presumptive positive for morphine.

(g) "Reporting Results."

(1) The HHS-certified laboratory shall report test results to the licensee's Medical Review Officer within 5 working days after

receipt of the specimen by the laboratory. Before any test result is reported (the results of initial tests, confirmatory tests, or quality control data), it shall be reviewed and the test certified as an accurate report by the responsible individual at the laboratory. The report shall identify the substances tested for, whether positive or negative, the cut-off(s) for each, the specimen number assigned by the licensee, and the drug testing laboratory specimen identification number. The results (positive and negative) for all specimens submitted at the same time to the laboratory shall be reported back to the Medical Review Officer at the same time when possible.

(2) The HHS-certified laboratory and any licensee testing facility shall report as negative all specimens, except suspect specimens being analyzed under special processing, which are negative on the initial test or negative on the confirmatory test. Specimens testing positive on the confirmatory analysis shall be reported positive for a specific substance. Presumptive positive results of preliminary testing at the licensee's testing facility will not be reported to licensee management.

(3) The Medical Review Officer may routinely obtain from the HHS-certified laboratory, and the laboratory shall provide, quantitation of test results. The Medical Review Officer may only disclose quantitation of test results for an individual to licensee management, if required in an appeals process, or to the individual under the provisions of Section 3.2. (This does not preclude the provision of program performance data under the provisions of 10 CFR 26.71(d).) Quantitation of negative tests for urine specimens shall not be disclosed, except where deemed appropriate by the Medical Review Officer for proper disposition of the results of tests of suspect specimens. Alcohol quantitation for a blood specimen shall be provided to licensee management with the Medical Review Officer's evaluation.

(4) The laboratory may transmit results to the Medical Review Officer by various electronic means (e.g., teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. Results may not be provided verbally by telephone from HHS-certified laboratory personnel to the Medical Review Officer. The HHS-certified laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(5) The laboratory shall send only to the Medical Review Officer a certified copy of the original chain-of-custody form signed by the individual responsible for day-to-day management of the drug testing laboratory or the individual responsible for attesting to the validity of the test reports and attached to which shall be a copy of the test report.

(6) The HHS-certified laboratory and the licensee's testing facility shall provide to the licensee official responsible for coordination of the fitness-for-duty program a monthly statistical summary of urinalysis and blood testing and shall not include in the summary any personal identifying information. Initial test data from the licensee's testing facility and the HHS-certified laboratory, and confirmation data from HHS-certified laboratories shall be included for test results reported within that month. Normally this summary shall be forwarded from HHS-certified laboratories by registered or certified mail and from the licensee's testing facility not more than 14 calendar days after the end of the month covered by the summary. The summary shall contain the following information:

(i) Initial Testing:

(A) Number of specimens received;

(B) Number of specimens reported out; and

(C) Number of specimens screened positive for:

Marijuana metabolites
Cocaine metabolites
Opiate metabolites
Phencyclidine
Amphetamines
Alcohol

(ii) Confirmatory Testing:

(A) Number of specimens received for confirmation;

(B) Number of specimens confirmed positive for:

Marijuana metabolite
Cocaine metabolite
Morphine, codeine
Phencyclidine
Amphetamine
Methamphetamine
Alcohol

(7) The statistics shall be presented for both the cut-off levels in these guidelines and any more stringent cut-off levels which licensees may specify. The HHS-certified laboratory and the licensee's testing facility shall make available quantitative results for all samples tested when requested by the NRC or the licensee for which the laboratory is performing drug testing services.

(8) Unless otherwise instructed by the licensee in writing, all records pertaining to a given urine or blood specimen shall be retained by the HHS-certified drug testing laboratory and the licensee's testing facility for a minimum of 2 years.

(h) "Long-Term Storage." Long-term frozen storage (−20 °C or less) ensures that positive urine specimens will be available for any necessary retest during administrative or disciplinary proceedings. Unless otherwise authorized in writing by the licensee, HHS-certified laboratories shall retain and place in properly secured long-term frozen storage for a minimum of 1 year all specimens confirmed positive. Within this 1-year period a licensee or the NRC may request the laboratory to retain the specimen for an additional period of time, but if no such request is received, the laboratory may discard the specimen after the end of 1 year, except that the laboratory shall be required to maintain any specimens under legal challenge for an indefinite period. Any split samples retained by the licensee shall be transferred into long-term storage upon determination by the Medical Review Officer that the specimen has a confirmed positive test.

(i) "Retesting Specimens." Because some analytes deteriorate or are lost during freezing and/or storage, quantitation for a retest is not subject to a specific cut-off requirement but must provide data sufficient to confirm the presence of the drug or metabolite.

(j) "Split Samples." Urine specimens may be split, at the licensee's discretion, into two parts at the collection site. One half of such samples (hereafter called the aliquot) shall be analyzed by the licensee's testing facility or the HHS-certified laboratory for the licensee's purposes as described in this appendix. The other half of the sample (hereafter called the split sample) may be withheld from transfer to the laboratory, sealed, and stored in a secure manner by the licensee until the aliquot has been determined to be negative or until the positive result of a screening test has been confirmed. As soon as the aliquot has tested negative, the split sample in storage may be destroyed. If the aliquot tests positive by confirmatory testing, then, at the tested individual's request, the split sample may be forwarded on that day to another HHS-certified laboratory that did not test the aliquot. The chain-of-custody and testing procedures to which the split sample is subject, shall be the same as those used to test the initial aliquot and shall meet the standards for retesting specimens [Section 2.7(i)]. The quantitative results of any second testing process shall be made available to the Medical Review Officer and to the individual tested.

(k) "Subcontracting." HHS-certified laboratories shall not subcontract and shall perform all work with their own personnel and equipment unless otherwise authorized by the licensee. The laboratory must be capable of performing testing of the five classes of drugs (marijuana, cocaine, opiates, phencyclidine, and amphetamines) and of whole blood and confirmatory GC/MS methods specified in these guidelines.

(l) "Laboratory Facilities."

(1) HHS-certified laboratories shall comply with applicable provisions of any State licensure requirements.

(2) HHS-certified laboratories shall have the capability, at the same laboratory premises, of performing initial tests for each drug and drug metabolite for which service is offered, and for performing confirmatory tests for alcohol and for each drug and drug metabolite for which service is offered. Any licensee testing facilities shall have the capability, at the same premises, of performing initial screening tests for each drug and drug metabolite for which testing is conducted. Breath tests for alcohol may be performed at the collection site.

(m) "Inspections." The NRC and any licensee utilizing an HHS-certified laboratory shall reserve the right to inspect the laboratory at any time. Licensee contracts with HHS-certified laboratories for drug testing and alcohol confirmatory testing, as well as contracts for collection site services, shall permit the NRC and the licensee to conduct unannounced inspections. In addition, prior to the award of a contract, the licensee shall carry out pre-award inspections and evaluation of the procedural aspects of the laboratory's drug testing operation. The NRC shall reserve the right to inspect a licensee's testing facility at any time.

(n) "Documentation." HHS-certified laboratories and the licensee's testing facility shall maintain and make available for at least 2 years documentation of all aspects of the testing process. This 2-year period may be extended upon written notification by the NRC or by any licensee for which laboratory services are being provided. The required documentation shall include personnel files on all individuals authorized to have access to specimens; chain-of-custody documents; quality assurance/quality control records; procedure manuals; all test data (including calibration curves and any calculations used in determining test results); reports; performance records on performance testing; performance on certification inspections; and hard copies of computer-generated data. The HHS-certified laboratory and the licensee's testing facility shall be required to maintain documents for any specimen under legal challenge for an indefinite period.

(o) "Additional Requirements for HHS-certified Laboratories and Licensee's Testing Facilities."

(1) "Procedure manual." Each laboratory and licensee's testing facility shall have a procedure manual which includes the principles of each test, preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of the methods, cutoff values, mechanisms for reporting results, controls, criteria for unacceptable specimens and results, remedial actions to be taken when the test systems are outside of acceptable limits, reagents and expiration dates, and references. Copies of all procedures and dates on which they are in effect shall be maintained as part of the manual. Superseded material must be retained for three years.

(2) "Standards and controls." HHS-certified laboratory standards shall be prepared with pure drug standards which are properly labeled as to content and concentration. The standards shall be labeled with the following dates: when received; when prepared or opened; when placed in service; and expiration date.

(3) "Instruments and equipment."

(i) Volumetric pipettes and measuring devices shall be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and dilutors shall be checked for accuracy and reproducibility before being placed in service and checked periodically thereafter.

(ii) Alcohol breath analysis equipment shall be an evidental-grade breath alcohol analysis device of a brand and model that conforms to National Highway Traffic Safety Administration (NHTSA) standards (49 FR 48855) and to any applicable State statutes.

(iii) There shall be written procedures for instrument set-up and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks, and instructions for major troubleshooting and repair. Records shall be available on preventive maintenance.

(4) "Remedial actions." There shall be written procedures for the actions to be taken when systems are out of acceptable limits or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

(5) "Personnel available to testify at proceedings." The licensee's testing facility and HHS-certified laboratory shall have qualified personnel available to testify in an administrative or disciplinary proceeding against an individual when that proceeding is based on positive breath analysis or urinalysis results reported by the licensee's testing facility or the HHS-certified laboratory.

2.8 Quality Assurance and Quality Control.

(a) "General." HHS-certified laboratories and the licensee's testing facility shall have a quality assurance program which encompasses all aspects of the testing process including but not limited to specimen acquisition, chain-of-custody, security, reporting of results, initial and confirmatory testing, and validation of analytical procedures. Quality assurance procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the process of testing for drugs.

(b) "Licensee's Testing Facility Quality Control Requirements for Initial Tests." Because all positive preliminary tests for drugs are forwarded to an HHS-certified laboratory for screening and confirmatory testing when appropriate, the NRC does not require licensees to assess their testing facility's false positive rates for drugs. To ensure that the rate of false negative tests is kept to the minimum that the immunoassay technology supports, licensees shall process blind performance test specimens and submit a sampling of specimens screened as negative from every test run to the HHS-certified laboratory. In addition, the manufacturer-required performance tests of the breath analysis equipment used by the licensee shall be conducted as set forth in the manufacturer's specifications.

(c) "Laboratory Quality Control Requirements for Initial Tests at HHS-Certified Laboratories." Each analytical run of specimens to be screened shall include:

(1) Urine specimens certified to contain no drug;

(2) Urine specimens fortified with known standards; and

(3) Positive controls with the drug or metabolite at or near the threshold (cut-off).

In addition, with each batch of samples, a sufficient number of standards shall be included to ensure and document the linearity of the assay method over time in the concentration area of the cut-off. After acceptable values are obtained for the known standards, those values will be used to calculate sample data. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall be documented. A minimum of 10 percent of all test samples shall be quality control specimens. Laboratory quality control samples, prepared from spiked urine samples of determined concentration, shall be included in the run and should appear as normal samples to laboratory analysts. One percent of each run, with a minimum of at least one sample, shall be the laboratory's own quality control samples.

(d) "Laboratory Quality Control Requirements for Confirmation Tests." Each analytical run of specimens to be confirmed shall include:

(1) Urine specimens certified to contain no drug;

(2) Urine specimens fortified with known standards; and

(3) Positive controls with the drug or metabolite at or near the threshold (cut-off).

The linearity and precision of the method shall be periodically documented. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall also be documented.

(e) "Licensee Blind Performance Test Procedures."

(1) Licensees shall purchase chemical testing services only from laboratories certified by DHHS or a DHHS-recognized certification program in accordance with the HHS Guidelines. Laboratory participation is encouraged in other performance testing surveys by which the laboratory's performance is compared with peers and reference laboratories.

(2) During the initial 90-day period of any new drug testing program, each licensee shall submit blind performance test specimens to each HHS-certified laboratory it contracts within the amount of at least 50 percent of the total number of samples submitted (up to a maximum of 500 samples) and thereafter a minimum of 10 percent of all samples (to a maximum of 250) submitted per quarter.

(3) Approximately 80 percent of the blind performance test samples shall be blank (i.e., certified to contain no drug) and the remaining samples shall be positive for one or more drugs per sample in a distribution such that all the drugs to be tested are included in approximately equal frequencies of challenge. The positive samples shall be spiked only with those drugs for which the licensee is testing.

(4) The licensee shall investigate, or shall refer to DHHS for investigation, any unsatisfactory performance testing result, and based on this investigation, the laboratory shall take action to correct the cause of the unsatisfactory performance test result. A record shall be made of the investigative findings and the corrective action taken by the laboratory, and that record shall be dated and signed by the individuals responsible for the day-to-day management and operation of the HHS-certified laboratory. Then the licensee shall send the document to the NRC as a report of the unsatisfactory performance testing incident within 30 days. The NRC shall ensure notification of the finding to DHHS.

(5) Should a false positive error occur on a blind performance test specimen and the error is determined to be an administrative error (clerical, sample mixup, etc.), the licensee shall promptly notify the NRC. The licensees shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future; and, if there is reason to believe the error could have been systematic, the licensee may also

require review and reanalysis of previously run specimens.

(6) Should a false positive error occur on a blind performance test specimen and the error is determined to be a technical or methodological error, the licensee shall instruct the laboratory to submit to them all quality control data from the batch of specimens which included the false positive specimen. In addition, the licensee shall require the laboratory to retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the individual responsible for day-to-day management of the laboratory's substance testing program. The licensee and the NRC may require an on-site review of the laboratory which may be conducted unannounced during any hours of operation of the laboratory. Based on information provided by the NRC, DHHS has the option of revoking or suspending the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

2.9 Reporting and Review of Results

(a) "Medical Review Officer shall review results." An essential part of the licensees' testing programs is the final review of results. A positive test result does not automatically identify a nuclear power plant worker as having used substances in violation of the NRC's regulations or the licensee's company policies. An individual with a detailed knowledge of possible alternate medical explanations is essential to the review of results. This review shall be performed by the Medical Review Officer prior to the transmission of results to licensee management officials.

(b) "Medical Review Officer—qualifications and responsibilities." The Medical Review Officer shall be a licensed physician with knowledge of substance abuse disorders and may be a licensee or contract employee. The role of the Medical Review Officer is to review and interpret positive test results obtained through the licensee's testing program. In carrying out this responsibility, the Medical Review Officer shall examine alternate medical explanations for any positive test result (this does not include confirmation of blood alcohol levels obtained through the use of a breath alcohol anaylsis device). This action could include conducting a medical interview with the individual, review of the individual's medical history, or review of any other relevant biomedical factors. The Medical Review Officer shall review all medical records made available by the tested individual when a confirmed positive test could have resulted from legally prescribed medication. The Medical Review Officer shall not consider the results of tests that are not obtained or processed in accordance with these Guidelines, although he or she may consider the results of tests on split samples in making his or her determination, as long as those split samples have been stored and tested in accordance with the procedures described in these Guidelines.

(c) "Positive Test Results." Prior to making a final decision to verify a positive test result, the Medical Review Officer shall give the individual an opportunity to discuss the test result with him or her. Following verification of a positive test result, the Medical Review Officer shall, as provided in the licensee's policy, notify the applicable employee assistance program and the licensee's management official empowered to recommend or take administrative action (or the official's designated agent).

(d) "Verification for opiates; review for prescription medication." Before the Medical Review Officer verifies a confirmed positive result and the licensee takes action for opiates, he or she shall determine that there is clinical evidence—in addition to the urine test—of unauthorized use of any opium, opiate, or opium derivative (e.g., morphine/codeine). Clinical signs of abuse include recent needle tracks or behavioral and psychological signs of acute opiate intoxication or withdrawal. This requirement does not apply if the GC/MS confirmation testing for opiates confirms the presence of 6-monoacetylmorphine. For other drugs that are commonly prescribed or commonly included in over-the-counter preparations (e.g., benzodiazepines in the first case, barbiturates in the second) and that are listed in the licensee's panel of substances to be tested, the Medical Review Officer shall also determine whether there is clinical evidence—in addition to the urine test—of unauthorized use of any of these substances or their derivatives.

(e) "Reanalysis authorized." Should any question arise as to the accuracy or validity of a positive test result, only the Medical Review Officer is authorized to order a reanalysis of the original sample and such retests are authorized only at laboratories certified by DHHS. The Medical Review Officer shall authorize a reanalysis of the original aliquot on timely request of the individual tested, and shall also authorize an analysis of any sample stored by the licensee.

(f) "Results consistent with responsible substance use." If the Medical Review Officer determines that there is a legitimate medical explanation for the positive test result and that use of the substance identified through testing in the manner and at the dosage prescribed does not reflect a lack of reliability and is unlikely to create on-the-job impairment, the Medical Review Officer shall report the test result to the licensee as negative.

(g) "Result scientifically insufficient." Additionally, the Medical Review Officer, based on review of inspection reports, quality control data, multiple samples, and other pertinent results, may determine that the result is scientifically insufficient for further action and declare the test specimen negative. In this situation, the Medical Review Officer may request reanalysis of the original sample before making this decision. (The Medical Review Officer may request that reanalysis be performed by the same laboratory or, that an aliquot of the original specimen be sent for reanalysis to an alternate laboratory which is certified in accordance with the HHS Guidelines.) The licensee's testing facility and the HHS-certified laboratory shall assist in this review process as requested by the Medical Review Officer by making available the individual(s) responsible for day-to-day management of the licensee's test facility, of the HHS-certified laboratory or other individuals who are forensic toxicologists or who have equivalent forensic experience in urine drug testing, to provide specific consultation as required by the licensee. The licensee shall maintain records that summarize any negative findings based on scientific insufficiency and shall make them available to the NRC on request, but shall not include any personal identifying information in such reports.

Subpart C—Employee Protection

3.1 Protection of Employee Records

Licensee contracts with HHS certified laboratories and procedures for the licensee's testing facility shall require that test records be maintained in confidence, as provided in 10 CFR 26.29. Records shall be maintained and used with the highest regard for individual privacy.

3.2 Individual Access to Test and Laboratory Certification Results

Any individual who is the subject of a drug or alcohol test under this part shall, upon written request, have access to any records relating to his or her tests and any records relating to the results of any relevant laboratory certification, review, or revocation-of-certification proceedings.

Subpart D—Certification of Laboratories Engaged in Chemical Testing

4.1 Use of DHHS-certified laboratories

(a) Licensees subject to this part and their contractors shall use only laboratories certified under the DHHS "Mandatory Guidelines for Federal Workplace Drug Testing Programs", Subpart C—"Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," (53 FR 11970, 11986–11989) dated April 11, 1988, and subsequent amendments thereto for screening and confirmatory testing except for initial screening tests at a licensee's testing facility conducted in accordance with 10 CFR 26.24(d). Information concerning the current certification status of laboratories is

available from: The Office of Workplace Initiatives, National Institute on Drug Abuse, 5600 Fishers Lane, Rockville, Maryland 20857.

(b) Licensees or their contractors may use only HHS-certified laboratories that agree to follow the same rigorous chemical testing, quality control, and chain-of-custody procedures when testing for more stringent cut-off levels as may be specified by licensees for the classes of drugs identified in this Part, for analysis of blood specimens for alcohol, and for any other substances included in licensees' drug panels.

Dated at Rockville, MD this 24th day of May, 1989.

For The Nuclear Regulatory Commission.

John C. Hoyle,

Acting Secretary of the Commission.

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